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 September 30, 2016

☐ **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	**31-1080091**
(State or other jurisdiction of incorporation or organization)	**(IRS Employer Identification No.)**
5600 Blazer Parkway, Suite 200, Dublin, Ohio	**43017-7550**
(Address of principal executive offices)	**(Zip Code)**

(614) 793-7500
(Registrant's telephone number, including area code)

(Former name, former address and former fiscal year, if changed since last report)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically 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, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐	Accelerated filer ☒
Non-accelerated filer ☐	Smaller reporting company ☐

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: 155,762,729 shares of common stock, par value $.001 per share (as of the close of business on November 1, 2016).

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

	September 30, 2016 (unaudited)	December 31, 2015
ASSETS		
Current assets:		
Cash	$ 810,425	$ 7,166,260
Restricted cash	3,501,247	—
Accounts and other receivables	3,474,329	3,703,186
Inventory, net	804,882	652,906
Prepaid expenses and other	839,978	1,054,822
Total current assets	9,430,861	12,577,174
Property and equipment	3,584,628	3,871,035
Less accumulated depreciation and amortization	2,210,554	1,943,427
	1,374,074	1,927,608
Patents and trademarks	222,590	233,596
Less accumulated amortization	41,604	47,438
	180,986	186,158
Other assets	203,679	273,573
Total assets	$ 11,189,600	$ 14,964,513
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 4,894,800	$ 1,767,523
Accrued liabilities and other	7,201,793	3,038,713
Deferred revenue, current	15,037	1,044,281
Notes payable, current	51,652,209	333,333
Total current liabilities	63,763,839	6,183,850
Deferred revenue	26,061	192,728
Notes payable, net of discounts of $0 and $2,033,506, respectively	10,549,405	60,746,002
Other liabilities	624,896	1,677,633
Total liabilities	74,964,201	68,800,213
Commitments and contingencies		
Stockholders' deficit:		
Preferred stock; $.001 par value; 5,000,000 shares authorized; no shares issued or outstanding at September 30, 2016 and December 31, 2015, respectively	—	—
Common stock; $.001 par value; 300,000,000 shares authorized, 155,751,316 issued and outstanding at September 30, 2016; 200,000,000 shares authorized, 155,649,665 shares issued and outstanding at December 31, 2015, respectively	155,751	155,650
Additional paid-in capital	326,573,833	326,085,743
Accumulated deficit	(390,973,227)	(380,546,651)
Total Navidea stockholders' deficit	(64,243,643)	(54,305,258)
Noncontrolling interest	469,042	469,558
Total stockholders' deficit	(63,774,601)	(53,835,700)
Total liabilities and stockholders' deficit	$ 11,189,600	$ 14,964,513

See accompanying notes to consolidated financial statements (unaudited).

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Revenue:				
Lymphoseek sales revenue	$ 6,690,090	$ 2,952,522	$ 14,704,489	$ 6,751,492
Lymphoseek license revenue	1,295,625	550,000	1,795,625	883,333
Grant and other revenue	511,359	476,755	2,113,995	1,320,816
Total revenue	8,497,074	3,979,277	18,614,109	8,955,641
Cost of goods sold	921,817	457,590	2,017,486	1,239,377
Gross profit	7,575,257	3,521,687	16,596,623	7,716,264
Operating expenses:				
Research and development	1,276,053	3,902,155	6,461,154	10,180,517
Selling, general and administrative	2,940,773	3,942,609	9,925,574	13,485,576
Total operating expenses	4,216,826	7,844,764	16,386,728	23,666,093
Income (loss) from operations	3,358,431	(4,323,077)	209,895	(15,949,829)
Other income (expense):				
Interest expense, net	(2,566,171)	(2,148,369)	(12,288,169)	(4,690,686)
Equity in loss of R-NAV, LLC	—	(26,785)	(15,159)	(295,217)
Loss on disposal of investment in R-NAV, LLC	—	—	(39,732)	—
Change in fair value of financial instruments	(839,298)	(1,577,275)	1,755,989	(1,702,902)
Loss on extinguishment of debt	—	—	—	(2,440,714)
Other, net	(12,498)	4,402	(49,916)	26,100
Total other expense, net	(3,417,967)	(3,748,027)	(10,636,987)	(9,103,419)
Net loss	(59,536)	(8,071,104)	(10,427,092)	(25,053,248)
Less loss attributable to noncontrolling interest	(159)	(340)	(516)	(681)
Deemed dividend on beneficial conversion feature of MT Preferred Stock	—	—	—	(46,000)
Net loss attributable to common stockholders	$ (59,377)	$ (8,070,764)	$ (10,426,576)	$ (25,098,567)
Loss per common share (basic and diluted)	$ (0.00)	$ (0.05)	$ (0.07)	$ (0.17)
Weighted average shares outstanding (basic and diluted)	155,481,278	150,186,131	155,390,911	150,030,638

See accompanying notes to consolidated financial statements (unaudited).

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

	Preferred Stock		Common Stock		Additional Paid-In	Accumulated	Non-controlling	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Interest	Deficit
Balance, December 31, 2015	—	$ —	155,649,665	$ 155,650	$326,085,743	$(380,546,651)	$ 469,558	$(53,835,700)
Issued restricted stock	—	—	168,000	168	—	—	—	168
Canceled forfeited restricted stock	—	—	(206,000)	(206)	178	—	—	(28)
Issued stock in payment of Board retainers	—	—	72,649	72	56,537	—	—	56,609
Issued stock to 401(k) plan	—	—	67,002	67	120,733	—	—	120,800
Stock compensation expense	—	—	—	—	310,642	—	—	310,642
Net loss	—	—	—	—	—	(10,426,576)	(516)	(10,427,092)
Balance, September 30, 2016	—	$ —	155,751,316	$ 155,751	$326,573,833	$(390,973,227)	$ 469,042	$(63,774,601)

See accompanying notes to consolidated financial statements (unaudited).

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

	Nine Months Ended September 30,	
	2016	2015
Cash flows from operating activities:		
Net loss	$ (10,427,092)	$ (25,053,248)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	378,834	431,368
Loss on disposal and abandonment of assets	136,719	33,184
Gain on forgiveness of accounts payable	(85,355)	—
Change in reserve for uncollectable accounts	—	16,000
Change in inventory reserve	43,354	138,914
Amortization of debt discount and issuance costs	77,964	423,522
Debt discount and issuance costs written off	1,955,541	—
Prepayment premium and debt collection fees related to long term debt	2,923,271	—
Compounded interest on long term debt	1,367,259	1,231,125
Stock compensation expense	310,642	1,916,179
Equity in loss of R-NAV, LLC	15,159	295,217
Loss on disposal of investment in R-NAV, LLC	39,732	—
Change in fair value of financial instruments	(1,755,989)	1,702,902
Loss on extinguishment of debt	—	2,440,714
Issued stock to 401(k) plan for employer matching contributions	120,800	117,099
Extension of warrant expiration date	—	149,615
Issued warrants in connection with advisory services agreement	—	256,450
Value of restricted stock issued to directors	56,609	131,262
Other	(15,159)	(53,642)
Changes in operating assets and liabilities:		
Accounts receivable	210,536	(1,108,828)
Inventory	(195,330)	(83,712)
Prepaid expenses and other assets	11,465	588,996
Accounts payable	3,212,632	(178,620)
Accrued and other liabilities	4,113,403	305,170
Deferred revenue	(1,195,911)	1,419,198
Net cash provided by (used in) operating activities	1,299,084	(14,881,135)
Cash flows from investing activities:		
Purchases of equipment	(1,847)	(30,406)
Proceeds from sales of equipment	45,000	38,265
Patent and trademark costs	—	(27,092)
Payments on disposal of investment in R-NAV, LLC	(110,000)	—
Proceeds from disposal of investment in R-NAV, LLC	27,623	—
Net cash used in investing activities	(39,224)	(19,233)
Cash flows from financing activities:		
Proceeds from issuance of MT Preferred Stock and warrants	—	500,000
Payment of preferred stock issuance costs	—	(12,587)
Proceeds from issuance of common stock, net	140	65,975
Payment of tax withholdings related to stock-based compensation	—	(23,906)
Proceeds from notes payable	—	54,500,000
Payment of debt-related costs	(3,923,271)	(3,902,487)
Principal payments on notes payable	(189,163)	(30,333,333)
Restricted cash held for payment against debt	(3,501,247)	—
Payments under capital leases	(2,154)	(1,880)
Net cash (used in) provided by financing activities	(7,615,695)	20,791,782
Net (decrease) increase in cash	(6,355,835)	5,891,414
Cash, beginning of period	7,166,260	5,479,006
Cash, end of period	$ 810,425	$ 11,370,420

See accompanying notes to consolidated financial statements (unaudited).

Notes to the Consolidated Financial Statements (unaudited)

1. Summary of Significant Accounting Policies

a. Basis of Presentation: The information presented as of September 30, 2016 and for the three-month and nine-month periods ended September 30, 2016 and 2015 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 September 30, 2016 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, 2015, 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. See Note 8.

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 3.

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. At September 30, 2016, restricted cash represents the balance in an account that is under the control of Capital Royalty Partners II L.P. (CRG). See Note 10. At September 30, 2016, approximately $894,000 of accounts payable was being disputed by the Company related to unauthorized expenditures by a former executive.

(2) Notes payable: The carrying value of our debt at September 30, 2016 and December 31, 2015 primarily consists of the face amount of the notes less unamortized discounts. See Note 9. At September 30, 2016 and December 31, 2015, 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 September 30, 2016, the fair value of our notes payable is approximately $62.2 million, equal to the carrying value of $62.2 million.

(3) Derivative liabilities: Derivative liabilities are related to certain outstanding warrants which are recorded at fair value. Derivative liabilities totaling $63,000 as of September 30, 2016 and December 31, 2015 were included in other liabilities on the consolidated balance sheets. The assumptions used to calculate fair value as of September 30, 2016 and December 31, 2015 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 3.

c. **Revenue Recognition:** We currently generate revenue primarily from sales of Lymphoseek® (technetium Tc 99m tilmanocept) injection. Our standard shipping terms are free on board (FOB) shipping point, and title and risk of loss passes to the customer upon delivery to a carrier for shipment. We generally recognize sales revenue related to sales of our products when the products are shipped. Our customers have no right to return products purchased in the ordinary course of business, however, we may allow returns in certain circumstances based on specific agreements.

We earn additional revenues based on a percentage of the actual net revenues achieved by Cardinal Health on sales to end customers made during each fiscal year. The amount we charge Cardinal Health related to end customer sales of Lymphoseek are subject to a retroactive annual adjustment. To the extent that we can reasonably estimate the end-customer prices received by Cardinal Health, we record sales based upon these estimates at the time of sale. If we are unable to reasonably estimate end customer sales prices related to products sold, we record revenue related to these product sales at the minimum (i.e., floor) price provided for under our distribution agreement with Cardinal Health.

During the nine-month periods ended September 30, 2016 and 2015, over 99% of Lymphoseek sales were made to Cardinal Health. As of September 30, 2016, approximately 81% of accounts and other receivables were due from Cardinal Health.

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 have determined that the license and other non-contingent deliverables do not have stand-alone value because the license could not be deemed to be fully delivered for its intended purpose unless we perform our other obligations, including specified development work. Accordingly, they do 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.

We generate additional revenue from grants to support various product development initiatives. We generally recognize grant revenue when expenses reimbursable under the grants have been paid and payments under the grants become contractually due. Lastly, we recognized revenues from the provision of services to R-NAV and its subsidiaries through the termination of the R-NAV joint venture on May 31, 2016. See Note 8.

d. **Recent Accounting Standards:** In August 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2014-15, *Presentation of Financial Statements-Going Concern.* ASU 2014-15 defines when and how companies are required to disclose going concern uncertainties, which must be evaluated each interim and annual period. ASU 2014-15 requires management to determine whether substantial doubt exists regarding the entity's going concern presumption. Substantial doubt about an entity's ability to continue as a going concern exists when relevant conditions and events, considered in the aggregate, indicate that it is probable that the entity will be unable to meet its obligations as they become due within one year after the date that the financial statements are issued (or available to be issued). If substantial doubt exists, certain disclosures are required; the extent of those disclosures depends on an evaluation of management's plans (if any) to mitigate the going concern uncertainty. ASU 2014-15 is effective prospectively for annual periods ending after December 15, 2016, and to annual and interim periods thereafter. Early adoption is permitted. We do not expect the adoption of ASU 2014-15 to have a material effect on our consolidated financial statements, however it may affect our disclosures.

In March 2016, the FASB issued ASU No. 2016-08, *Revenue from Contracts with Customers – Principal versus Agent Considerations (Reporting Revenue Gross versus Net)*. ASU 2016-08 does not change the core principle of the guidance, rather it clarifies the implementation guidance on principal versus agent considerations. ASU 2016-08 clarifies the guidance in ASU No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*, which is not yet effective. The effective date and transition requirements for ASU 2016-08 are the same as for ASU 2014-09, which was deferred by one year by ASU No. 2015-14, *Revenue from Contracts with Customers – Deferral of the Effective Date*. Public business entities should adopt the new revenue recognition standard for annual reporting periods beginning after December 15, 2017, including interim periods within that year. Early adoption is permitted only as of annual reporting periods beginning after December 15, 2016, including interim periods within that year. We are currently evaluating the potential impact that the adoption of ASU 2014-09 may have on our consolidated financial statements.

In March 2016, the FASB issued ASU No. 2016-09, *Compensation – Stock Compensation.* 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. Some of the simplified areas apply only to nonpublic entities. ASU 2016-09 is effective for public business entities for annual periods beginning after December 15, 2016, and interim periods within those annual periods. Early adoption is permitted in any interim or annual period. If an entity early adopts ASU 2016-09 in an interim period, any adjustments should be reflected as of the beginning of the fiscal year that includes that interim period. Methods of adoption vary according to each of the amendment provisions. We are currently evaluating the potential impact that the adoption of ASU 2016-09 may have on our consolidated financial statements.

In April 2016, the FASB issued ASU No. 2016-10, *Revenue from Contracts with Customers – Identifying Performance Obligations and Licensing.* ASU 2016-10 does not change the core principle of the guidance, rather it clarifies the identification of performance obligations and the licensing implementation guidance, while retaining the related principles for those areas. ASU 2016-10 clarifies the guidance in ASU No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*, which is not yet effective. The effective date and transition requirements for ASU 2016-10 are the same as for ASU 2014-09, which was deferred by one year by ASU No. 2015-14, *Revenue from Contracts with Customers – Deferral of the Effective Date.* Public business entities should adopt the new revenue recognition standard for annual reporting periods beginning after December 15, 2017, including interim periods within that year. Early adoption is permitted only as of annual reporting periods beginning after December 15, 2016, including interim periods within that year. We are currently evaluating the potential impact that the adoption of ASU 2014-09 may have on our consolidated financial statements.

In May 2016, the FASB issued ASU No. 2016-12, *Revenue from Contracts with Customers – Narrow-Scope Improvements and Practical Expedients*. ASU 2016-12 does not change the core principle of the guidance, rather it affects only certain narrow aspects of Topic 606, including assessing collectability, presentation of sales taxes, noncash consideration, and completed contracts and contract modifications at transition. ASU 2016-12 affects the guidance in ASU No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*, which is not yet effective. The effective date and transition requirements for ASU 2016-12 are the same as for ASU 2014-09, which was deferred by one year by ASU No. 2015-14, *Revenue from Contracts with Customers – Deferral of the Effective Date*. Public business entities should adopt the new revenue recognition standard for annual reporting periods beginning after December 15, 2017, including interim periods within that year. Early adoption is permitted only as of annual reporting periods beginning after December 15, 2016, including interim periods within that year. We are currently evaluating the potential impact that the adoption of ASU 2014-09 may have on our consolidated financial statements.

In August 2016, the FASB issued ASU No. 2016-15, *Statement of Cash Flows – Classification of Certain Cash Receipts and Cash Payments*. ASU 2016-15 addresses certain specific cash flow issues with the objective of reducing the existing diversity in practice in how certain cash receipts and cash payments are presented and classified in the statement cash flows. ASU 2016-15 is effective for public business entities for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. Early adoption is permitted in any interim or annual period. If an entity early adopts ASU 2016-15 in an interim period, any adjustments should be reflected as of the beginning of the fiscal year that includes that interim period. ASU 2016-15 should be applied using a retrospective transition method to each period presented, with certain exceptions. We adopted ASU 2016-15 upon issuance, which resulted in debt prepayment costs being classified as financing costs rather than operating costs on the statement of cash flows.

e. Reclassifications: Certain reclassifications have been made to the prior year's financial statements to conform to the 2016 presentation. The reclassifications relate to the presentation of the consolidated statements of cash flows and do not change the consolidated balance sheets, statements of operations, or net cash used in operating activities.

2. Liquidity

All of our material assets, except our intellectual property, have been 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 carries covenants that impose significant requirements on us, including, among others, requirements that we (1) pay all principal, interest and other charges on the outstanding balance of the borrowed funds when due; (2) maintain liquidity of at least $5 million during the term of the CRG Loan Agreement; and (3) meet certain annual EBITDA or revenue targets ($22.5 million of Lymphoseek sales revenue in 2016) as defined in the CRG Loan Agreement. The events of default under the CRG Loan Agreement also include a failure of 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) to perform its funding obligations under the Platinum Loan Agreement (as defined below) at any time as to which the Company had negative EBITDA for the most recent fiscal quarter, as a result either of Platinum's repudiation of its obligations under the Platinum Loan Agreement, or

the occurrence of an insolvency event with respect to Platinum. An event of default would entitle 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.

During the second quarter 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.

On July 13, 2016, a hearing was held in the District Court of Harris County, Texas with respect to an application for temporary injunction (ATI) filed by CRG in June 2016. At the conclusion of the hearing, the Court ordered the parties to mediation and stayed any ruling on CRG's request for injunctive relief until after a mediation has been completed. On July 20, the parties participated in mediation but were not successful in reaching an agreement. On July 29, 2016, the Harris County, Texas judge recused herself from the case, citing inability to be impartial. A new judge was appointed on July 29, 2016.

On August 30, 2016, the District Court of Harris County, Texas granted CRG's ATI. The Court provided the Company with 21 days to enter into the requisite account control agreements with CRG. In September 2016, the ATI was superseded by the requirement to maintain $2.5 million in a pledged collateral account that is subject to an account control agreement. The Order granting the ATI is currently on appeal to the Fourteenth Court of Appeals. Briefing is expected to be completed by early December 2016, after which a date will be set for oral arguments.

Discovery is ongoing in the Texas court action; the discovery period ends June 23, 2017. CRG filed an objection to the supersedeas that was heard on October 31, 2016, during which the court ruled that an additional $500,000 should be placed in the pledged collateral account within ten days of the ruling. In addition, CRG has filed a motion for partial summary judgment that currently is set for hearing on December 12, 2016. The Company is preparing responses to the motion for partial summary judgment. The trial date is currently set for July 3, 2017.

In June 2016, CRG contacted our primary distribution partner, Cardinal Health, and demanded that Cardinal Health make all future payments for Lymphoseek sales directly to CRG, rather than to Navidea. Cardinal Health filed an interpleader in the Franklin County, Ohio Court of Common Pleas, requesting that the court make a determination as to whom Cardinal Health should make such payments. Rulings on June 28, 2016 and August 1, 2016 resulted in $1.0 million of Cardinal Health payments being placed in escrow with the court, with the remaining Cardinal Health payments going directly to the Company.

In October 2016, a revised temporary restraining order was issued, allowing the Company to receive 100% of the receivables due from Cardinal Health, with an additional $1.0 million deposited in the pledged collateral account by the Company as a bond. Further, the court ruled that the Company remain current on its quarterly interest payments to CRG. On October 7, 2016 the Company paid $1.3 million to CRG to cover the third quarter 2016 interest payment. The $1.0 million previously deposited by Navidea in the Court's registry as a bond will also be transferred to the pledged collateral account. CRG has filed a motion to dismiss the Company's cross-claims in Cardinal Health's Franklin County, Ohio interpleader action. The Company is in the process of responding to CRG's motion to dismiss.

As of September 30, 2016, the Company's unrestricted cash balance was $810,000, with $3.5 million restricted cash in the pledged collateral and court escrow accounts.

The Company maintains that CRG's allegations of multiple events of default under the CRG Loan Agreement are without merit and the Company believes it has defenses against these claims. Furthermore, the Company believes that CRG's actions constitute a material breach of the CRG Loan Agreement and therefore, the Company is no longer subject to certain provisions of the CRG Loan Agreement. The Company believes that its best course of action is to pay off or refinance the CRG debt and pursue its claims for damages. The Company is continuing to explore alternative financing arrangements, including the Proposed Transaction with Cardinal Health discussed below, in order to pay off or refinance the CRG debt. There can be no assurance that CRG will not prevail in exercising control over any additional banking arrangements that the Company creates, that the Company will be able to pay off or refinance the CRG debt or that the Company will be successful in its claims for damages. In light of current circumstances, the ability of the Company to continue as a going concern is in substantial doubt and dependent upon its ability to generate sufficient cash flow to sustain its operations on a timely basis, to obtain additional financing as may be required, and to refinance the CRG debt. See Notes 9 and 10.

In addition, our Loan Agreement with Platinum (the Platinum Loan Agreement) carries standard non-financial covenants typical for commercial loan agreements, many of which are similar to those contained in the CRG Loan Agreement, 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 terminate our ability to obtain additional draws under the Platinum Loan Agreement and accelerate the maturity of the debt, subject to the limitations of the Subordination Agreement

with CRG. Such actions by Platinum could materially adversely affect our operations, results of operations and financial condition, including causing us to substantially 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.

As of September 30, 2016, the outstanding principal balance of the Platinum Note was approximately $9.3 million, with $27.3 million currently available under the credit facility. An additional $15 million is potentially available under the credit facility on terms to be negotiated. However, based on Platinum's recent filing for Chapter 15 bankruptcy protection, Navidea has substantial doubt about Platinum's ability to fund future draw requests under the credit facility. The inability to access credit under the Platinum Loan Agreement or other potentially available arrangements could materially adversely affect our operations and financial condition and our ability to continue as a going concern. See Note 9.

On September 5, 2016, the Company entered into a non-binding letter of intent (LOI) with Cardinal Health pursuant to which Cardinal Health intends to acquire the Company's Lymphoseek product (the Product) and certain intellectual property rights and other assets related to the Product (the Acquired Assets) and assume certain liabilities associated with the Acquired Assets (the Proposed Transaction). The purchase price for the Proposed Transaction shall consist of (i) $80 million in cash payable at closing (reduced to the extent the amount of transferred Product inventory is less than $6 million), plus (ii) annual earn-out and milestone payments based upon the volume of Product sales. For the first three years, the earn-out payments shall be no less than $6.7 million per year. In no event will the entire purchase price, including all earn-out payments, exceed $310 million.

As part of the Proposed Transaction, the parties have agreed that simultaneous with the closing, subject to certain conditions, Cardinal Health will license to the Company (License Back), on a perpetual royalty free basis, certain rights to the Acquired Assets necessary for the Company to (i) develop, manufacture, market, sell and distribute new pharmaceutical and other products on an exclusive basis so long as such products do not compete with the Product, and (ii) manufacture, market, sell and distribute the Product throughout the world other than in North America on a non-exclusive basis.

Also as part of the Proposed Transaction, the Company shall grant to Cardinal Health five (5) year warrants to purchase up to 10 million shares of the Company's common stock, par value $.001 per share, at an exercise price of $1.50 per share and provide Cardinal Health with a right of first offer related to the assets covered by the License Back and new products developed by the Company in certain circumstances during the life of the Product's patents.

The parties intend to negotiate and execute definitive agreements for the Proposed Transaction with customary provisions for a transaction of this size and scope, including representations and warranties regarding the Company, its business, and the Acquired Assets, indemnification of Cardinal Health by the Company, covenants and closing conditions. The closing of the Proposed Transaction is subject to, among other things, the satisfactory completion of due diligence by Cardinal Health and approval of the Company's stockholders.

Unless written notice is given to the Company that Cardinal Health is ceasing further discussions related to the Proposed Transaction, the Company has agreed not to initiate or enter into any discussions with any third party regarding a possible sale of any equity or material assets of the Company or its subsidiaries for a period of thirty days from the date of the LOI. If the Company does not consummate a transaction with Cardinal Health as contemplated by the LOI and at any time within 180 days of the date of the LOI consummates one or more transactions that, directly or indirectly, result in a sale, license or other transfer of the Product, or all or substantially all of the Company's assets, then a certain Supply and Distribution Agreement between the Company and Cardinal Health shall automatically be extended for an additional three-year period. The parties have agreed that the provisions described in this paragraph shall be binding.

The Company intends to use the majority of the initial proceeds from the Proposed Transaction to pay off the loans to CRG and Platinum, and use the remainder to fund operations in the near term. If the Proposed Transaction closes, it will significantly improve our financial condition and our ability to continue as a going concern.

3. Fair Value

Platinum 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. Platinum's debt instrument, including the embedded option to convert such debt into common stock, is recorded at fair value on the consolidated balance sheets. The estimated fair value of the Platinum notes payable is $10.5 million at September 30, 2016.

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 September 30, 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 September 30, 2016

Description	Quoted Prices in Active Markets for Identical Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Platinum notes payable conversion option	$ —	$ —	$ 1,255,891	$ 1,255,891
Liability related to MT warrants	—	—	63,000	63,000

Liabilities Measured at Fair Value on a Recurring Basis as of December 31, 2015

Description	Quoted Prices in Active Markets for Identical Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Platinum notes payable conversion option	$ —	$ —	$ 3,011,880	$ 3,011,880
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.

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 nine-month periods ended September 30, 2016 and 2015. There were no transfers in or out of Level 1 or Level 2 liabilities during the nine-month periods ended September 30, 2016 and 2015. 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 September 30, 2016 and 2015 was increases of $839,000 and $1.6 million, respectively. The change in the estimated fair value of our Level 3 liabilities during the nine-month periods ended September 30, 2016 and 2015 was a decrease of $1.8 million and an increase of $1.7 million, respectively.

4. Stock-Based Compensation

For the three-month periods ended September 30, 2016 and 2015, our total stock-based compensation expense, which includes reversals of expense for certain forfeited or cancelled awards, was approximately $50,000 and $397,000, respectively. For the nine-month periods ended September 30, 2016 and 2015, our total stock-based compensation expense, which includes reversals of expense for certain forfeited or cancelled awards, was approximately $311,000 and $1.9 million, respectively. We have not recorded any income tax benefit related to stock-based compensation in any of the three-month or nine-month periods ended September 30, 2016 and 2015.

A summary of the status of our stock options as of September 30, 2016, and changes during the nine-month period then ended, is presented below:

	Nine Months Ended September 30, 2016			
	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value
Outstanding at beginning of period	5,437,064	$ 1.96		
Granted	459,457	1.05		
Exercised	—	—		
Canceled and Forfeited	(1,900,790)	1.66		
Expired	(299,000)	2.42		
Outstanding at end of period	3,696,731	$ 1.97	6.7 years	$ 90,039
Exercisable at end of period	2,602,167	$ 2.04	6.2 years	$ 88,815

A summary of the status of our unvested restricted stock as of September 30, 2016, and changes during the nine-month period then ended, is presented below:

	Nine Months Ended September 30, 2016	
	Number of Shares	Weighted Average Grant-Date Fair Value
Unvested at beginning of period	361,000	$ 1.69
Granted	168,000	1.20
Vested	(66,000)	1.65
Forfeited	(206,000)	1.77
Unvested at end of period	257,000	$ 1.32

During the nine-month period ended September 30, 2016, 66,000 shares of restricted stock held by non-employee directors with an aggregate fair value of $63,360 vested as scheduled according to the terms of the restricted stock agreements. Also during the nine-month period ended September 30, 2016, 206,000 shares of unvested restricted stock were forfeited upon resignation of certain directors and an officer.

As of September 30, 2016, there was approximately $374,000 of total unrecognized compensation expense related to unvested stock-based awards, which we expect to recognize over the remaining weighted average vesting term of 1.2 years.

5. 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.

Diluted earnings (loss) per common share for the nine-month periods ended September 30, 2016 and 2015 excludes the effects of 14.5 million and 19.3 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 operations, 257,000 shares of unvested restricted stock for the three-month and nine-month periods ended September 30, 2016, and 503,500 shares of unvested restricted stock for the three-month and nine-month periods ended September 30, 2015, respectively, were excluded in determining basic and diluted loss per share because such inclusion would be anti-dilutive.

6. Inventory

All components of inventory are valued at the lower of cost (first-in, first-out) or market. We adjust inventory to market value when the net realizable value is lower than the carrying cost of the inventory. Market 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 September 30, 2016 and December 31, 2015 are as follows:

	September 30, 2016 (unaudited)	December 31, 2015
Materials	$ 517,650	$ 330,000
Work-in-process	65,611	392,457
Finished goods	442,881	275,168
Reserves	(221,260)	(344,719)
Total	$ 804,882	$ 652,906

During the nine month-period ended September 30, 2015, we wrote off $120,000 of materials related to production issues. During the nine-month periods ended September 30, 2016 and 2015, the Company used $45,000 and $184,000, respectively, of Lymphoseek inventory for clinical study and product development purposes.

7. Investment in Macrophage Therapeutics, Inc.

In December 2015 and May 2016, Platinum contributed a total of $200,000 to MT. MT was not obligated to provide anything in return, although it was considered likely that the MT Board would ultimately authorize some form of compensation to Platinum. As such, the Company recorded the $200,000 as a current liability pending determination of the form of compensation.

In July 2016, MT's Board of Directors authorized modification of the original investments of $300,000 by Platinum and $200,000 by Dr. Goldberg 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 preferred will remain at the $500 million initial market cap but a full ratchet will be 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 authorized issuance of additional convertible preferred stock with the same terms to Platinum as compensation for the additional $200,000 of investments made in December 2015 and May 2016. 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.

8. Investment in R-NAV, LLC

Effective May 31, 2016, Navidea terminated its joint venture with R-NAV. Under the terms of the agreement, Navidea (1) transferred all of its shares of R-NAV, consisting of 1,500,000 Series A Preferred Units and 3,500,000 Common Units, to R-NAV; and (2) paid $110,000 in cash to R-NAV. In exchange, R-NAV (1) transferred all of its shares of TcRA Imaging, Inc. (TcRA) to Navidea, thereby returning the technology licensed to TcRA to Navidea; and (2) forgave the $333,333 remaining on the promissory note. Neither Navidea nor R-NAV has any further obligations of any kind to either party. As a result of this transaction, the Company recognized a loss on disposal of the investment in R-NAV of $39,732 during the second quarter of 2016.

Navidea's investment in R-NAV was being accounted for using the equity method of accounting. Navidea's equity in the loss of R-NAV was $15,159 and $268,432, respectively, for the nine-month periods ended September 30, 2016 and 2015. Navidea's equity in the loss of R-NAV exceeded our initial investment in R-NAV. As such, the carrying value of the Company's investment in R-NAV was $0 as of the date of termination.

The Company's obligation to provide $500,000 of in-kind services to R-NAV was being recognized as those services were provided. The Company provided $15,000 and $27,000, respectively, of in-kind services during the nine-month periods ended September 30, 2016 and 2015. As of the date of termination, the Company had $383,000 of in-kind services remaining to provide under this obligation. This obligation ceased on May 31, 2016 under the terms of the agreement.

Navidea provided additional services to R-NAV in support of its development activities. Such services were immaterial to Navidea's overall operations.

9. Notes Payable

Platinum

In July 2012, we entered into an agreement with Platinum to provide us with a credit facility of up to $50 million. Following the approval of Lymphoseek, Platinum was committed under the terms of the agreement to extend up to $35 million in debt financing to the Company. During the nine-month period ended September 30, 2016, $814,000 of interest was compounded and added to the balance of the Platinum Note. In accordance with the terms of a Section 16(b) Settlement Agreement, Platinum agreed to forgive interest owed on the credit facility in an amount equal to 6%, effective July 1, 2016. As of September 30, 2016, the outstanding principal balance of the Platinum Note was approximately $9.3 million, with $27.3 million currently available under the credit facility. An additional $15 million is potentially available under the credit facility on terms to be negotiated. However, based on Platinum's recent filing for Chapter 15 bankruptcy protection, Navidea has substantial doubt about Platinum's ability to fund future draw requests under the credit facility.

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 $1.3 million. During the three-month periods ended September 30, 2016 and 2015, changes in the estimated fair value of the Platinum conversion option were increases of $839,000 and $1.6 million, respectively, and were recorded as non-cash changes in the fair value of the conversion option. During the nine-month periods ended September 30, 2016 and 2015, changes in the estimated fair value of the Platinum conversion option were a decrease of $1.8 million and an increase of $1.7 million, respectively, and were recorded as non-cash changes in the fair value of the conversion option. The estimated fair value of the Platinum Note was $10.5 million as of September 30, 2016.

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.

Capital Royalty Partners II, L.P.

In May 2015, Navidea and its subsidiary Macrophage Therapeutics, Inc., as guarantor, executed a Term Loan Agreement with CRG in its capacity as a lender and as control agent for other affiliated lenders party to the CRG Loan Agreement (collectively, the Lenders) in 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 nine-month period ended September 30, 2016, $553,000 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, the Company stopped compounding interest in the second quarter of 2016 and began recording accrued interest. As of September 30, 2016, $4.7 million of accrued interest is included in accrued liabilities and other on the consolidated balance sheets. As of September 30, 2016, the outstanding principal balance of the CRG Term Loan was $51.7 million.

In connection with the CRG Loan Agreement, the Company recorded a debt discount related to lender fees and other costs directly attributable to the CRG Loan Agreement totaling $2.2 million, including a $1.0 million facility fee which is payable at the end of the term or when the loan is repaid in full. A long-term liability was recorded for the $1.0 million facility fee. The debt discount was being amortized as non-cash interest expense using the effective interest method over the term of the CRG Loan Agreement. As further described below, the facility fee was fully paid off and the debt discount was accelerated and fully amortized in the second quarter of 2016.

The CRG Term Loan is collateralized by a security interest in substantially all of the Company's assets. In addition, the CRG Loan Agreement requires that the Company adhere to certain affirmative and negative covenants, including financial reporting requirements and a prohibition against the incurrence of indebtedness, or creation of additional liens, other than as specifically permitted by the terms of the CRG Loan Agreement. The Lenders may accelerate the payment terms of the CRG Loan Agreement upon the occurrence of certain events of default set forth therein, which include the failure of the Company to make timely payments of amounts due under the CRG Loan Agreement, the failure of the Company to adhere to the covenants set forth in the CRG Loan Agreement, and the insolvency of the Company. The covenants of the CRG Loan Agreement include a covenant that the Company shall have EBITDA of no less than $5 million in each calendar year during the term or revenues from sales of Lymphoseek in each calendar year during the term of at least $22.5 million in 2016, with the target minimum revenue increasing in each year thereafter until reaching $45 million in 2020. However, if the Company were to fail to meet the applicable minimum EBITDA or revenue target in any calendar year, the CRG Loan Agreement provides the Company a cure right if it raises 2.5 times the EBITDA or revenue shortfall in equity or subordinated debt and deposits such funds in a separate blocked account. Additionally, the Company must maintain liquidity, defined as the balance of unencumbered cash and permitted cash equivalent

investments, of at least $5 million during the term of the CRG Term Loan. The events of default under the CRG Loan Agreement also include a failure of Platinum to perform its funding obligations under the Platinum Loan Agreement at any time as to which the Company had negative EBITDA for the most recent fiscal quarter, as a result either of Platinum's repudiation of its obligations under the Platinum Loan Agreement, or the occurrence of an insolvency event with respect to Platinum. An event of default would entitle 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.

During the second quarter 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. CRG subsequently notified the Company that the cash was used to reimburse CRG for actual costs and expenses incurred by CRG related to the collection of the collateral of $778,000, pay the prepayment premium of $2.1 million and the backend facility fee of $1.0 million, and the remaining $189,000 was applied to the principal balance of the loan. The collection fees and prepayment premium were recorded as interest expense, the backend facility fee reduced the liability that was recorded for that purpose at inception, and the principal payment reduced the balance of the debt during the second quarter of 2016. In addition, the remaining unamortized balance of the debt discount of $2.0 million was recorded as interest expense during the second quarter of 2016. Although we have conservatively categorized these expenses according to the manner in which CRG applied them, we believe the $4.1 million should be applied entirely to the outstanding principal balance of the loan.

On July 13, 2016, a hearing was held in the District Court of Harris County, Texas with respect to an application for temporary injunction (ATI) filed by CRG in June 2016. At the conclusion of the hearing, the Court ordered the parties to mediation and stayed any ruling on CRG's request for injunctive relief until after a mediation has been completed. On July 20, the parties participated in mediation but were not successful in reaching an agreement. On July 29, 2016, the Harris County, Texas judge recused herself from the case, citing inability to be impartial. A new judge was appointed on July 29, 2016.

On August 30, 2016, the District Court of Harris County, Texas granted CRG's ATI. The Court provided the Company with 21 days to enter into the requisite account control agreements with CRG. In September 2016, the ATI was superseded by the requirement to maintain $2.5 million in a pledged collateral account that is subject to an account control agreement. The Order granting the ATI is currently on appeal to the Fourteenth Court of Appeals. Briefing is expected to be completed by early December 2016, after which a date will be set for oral arguments.

Discovery is ongoing in the Texas court action; the discovery period ends June 23, 2017. CRG filed an objection to the supersedeas that was heard on October 31, 2016, during which the court ruled that an additional $500,000 should be placed in the pledged collateral account within ten days of the ruling. In addition, CRG has filed a motion for partial summary judgment that currently is set for hearing on December 12, 2016. The Company is preparing responses to the motion for partial summary judgment. The trial date is currently set for July 3, 2017.

In June 2016, CRG contacted our primary distribution partner, Cardinal Health, and demanded that Cardinal Health make all future payments for Lymphoseek sales directly to CRG, rather than to Navidea. Cardinal Health filed an interpleader in the Franklin County, Ohio Court of Common Pleas, requesting that the court make a determination as to whom Cardinal Health should make such payments. Rulings on June 28, 2016 and August 1, 2016 resulted in $1.0 million of Cardinal Health payments being placed in escrow with the court, with the remaining Cardinal Health payments going directly to the Company.

In October 2016, a revised temporary restraining order was issued, allowing the Company to receive 100% of the receivables due from Cardinal Health, with an additional $1 million deposited in the pledged collateral account by the Company as a bond. Further, the court ruled that the Company remain current on its quarterly interest payments to CRG. On October 7, 2016 the Company paid $1.3 million to CRG to cover the third quarter 2016 interest payment. The $1.0 million previously deposited by Cardinal Health in the Court's registry as a bond will also be transferred to the pledged collateral account. CRG has filed a motion to dismiss the Company's cross-claims in Cardinal Health's interpleader action. The Company is in the process of responding to CRG's motion to dismiss.

The Company maintains that CRG's allegations of multiple events of default under the CRG Loan Agreement are without merit and the Company believes it has defenses against these claims. Furthermore, the Company believes that CRG's actions constitute a material breach of the CRG Loan Agreement and therefore, the Company is no longer subject to certain provisions of the CRG Loan Agreement. The Company believes that its best course of action is to pay off or refinance the CRG debt and pursue claims for damages. The Company is continuing to explore alternative financing arrangements, including the Proposed Transaction with Cardinal Health, in order to pay off or refinance the CRG debt. There can be no assurance that CRG will not prevail in exercising control over any additional banking arrangements that the Company creates, that the Company will be able to pay off or refinance the CRG debt or that the Company will be successful in its claims for damages. In light of current circumstances, the ability of the Company to continue as a going concern is in substantial doubt and dependent upon its ability to generate sufficient cash flow to sustain its operations on a timely basis, to obtain additional financing as may be required, and to pay off or refinance the CRG debt. See Notes 2 and 10.

Based on CRG's claims that the Company is in default under the terms of the CRG Loan Agreement, and in accordance with current accounting guidance, the Company has classified the balance of the CRG Term Loan as a current liability as of September 30, 2016.

R-NAV, LLC

Effective May 31, 2016, Navidea terminated its joint venture with R-NAV. In accordance with the terms of the agreement, R-NAV forgave the $333,333 remaining on the promissory note. See Note 8.

Summary

During the three-month periods ended September 30, 2016 and 2015, we recorded net interest expense of $2.6 million and $2.1 million, respectively, primarily related to our notes payable. Of these amounts, $0 and $65,000, respectively, related to amortization of the debt discounts related to our notes payable. An additional $190,000 and $802,000, respectively, of total interest expense was compounded and added to the balance of our notes payable during the three-month periods ended September 30, 2016 and 2015. During the nine-month periods ended September 30, 2016 and 2015, we recorded net interest expense of $12.3 million and $4.7 million, respectively, primarily related to our notes payable. Of these amounts, $78,000 and $424,000, respectively, related to amortization of the debt discounts related to our notes payable. An additional $1.4 million and $1.2 million, respectively, of total interest expense was compounded and added to the balance of our notes payable during the nine-month periods ended September 30, 2016 and 2015. The collection fees of $778,000, prepayment premium of $2.1 million, and the remaining unamortized balance of the CRG debt discount of $2.0 million were also recorded as interest expense during the nine-month period ended September 30, 2016.

10. Commitments and Contingencies

Sinotau Litigation

On August 31, 2015, Sinotau Pharmaceutical Group (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 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.

In July 2016, the Company executed a term sheet with Cerveau Technologies, Inc. (Cerveau) as a designated party for the rights resulting from the relationship between Navidea and Sinotau. The term sheet outlined the terms of a potential agreement between the parties to sublicense NAV4694 to Cerveau in return for license fees, milestone payments and royalties. With the exception of certain provisions, the term sheet was non-binding and was subject to the agreement of AstraZeneca, from whom the Company has licensed the NAV4694 technology. The Company had 60 days to execute a definitive agreement, however no definitive agreement was reached. Discussions related to the potential partnering or divestiture of NAV4694 are ongoing.

CRG Litigation

During the second quarter 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. CRG subsequently notified the Company that the cash was used to reimburse CRG for actual costs and expenses incurred by CRG related to the collection of the collateral of $778,000, pay the prepayment premium of $2.1 million and the backend facility fee of $1.0 million, and the remaining $189,000 was applied to the principal balance of the loan.

On July 13, 2016, a hearing was held in the District Court of Harris County, Texas with respect to an application for temporary injunction (ATI) filed by CRG in June 2016. At the conclusion of the hearing, the Court ordered the parties to mediation and stayed any ruling on CRG's request for injunctive relief until after a mediation has been completed. On July 20, the parties participated in mediation but were not successful in reaching an agreement. On July 29, 2016, the Harris County, Texas judge recused herself from the case, citing inability to be impartial. A new judge was appointed on July 29, 2016.

On August 30, 2016, the District Court of Harris County, Texas granted CRG's ATI. The Court provided the Company with 21 days to enter into the requisite account control agreements with CRG. In September 2016, the ATI was superseded by the requirement to maintain $2.5 million in a pledged collateral account that is subject to an account control agreement. The Order granting the ATI is currently on appeal to the Fourteenth Court of Appeals. Briefing is expected to be completed by early December 2016, after which a date will be set for oral arguments.

Discovery is ongoing in the Texas court action; the discovery period ends June 23, 2017. CRG filed an objection to the supersedeas that was heard on October 31, 2016, during which the court ruled that an additional $500,000 should be placed in the pledged collateral account within ten days of the ruling. In addition, CRG has filed a motion for partial summary judgment that currently is set for hearing on December 12, 2016. The Company is preparing responses to the motion for partial summary judgment. The trial date is currently set for July 3, 2017.

In June 2016, CRG contacted our primary distribution partner, Cardinal Health, and demanded that Cardinal Health make all future payments for Lymphoseek sales directly to CRG, rather than to Navidea. Cardinal Health filed an interpleader in the Franklin County, Ohio Court of Common Pleas, requesting that the court make a determination as to whom Cardinal Health should make such payments. Rulings on June 28, 2016 and August 1, 2016 resulted in $1.0 million of Cardinal Health payments being placed in escrow with the court, with the remaining Cardinal Health payments going directly to the Company.

In October 2016, a revised TRO was issued, allowing the Company to receive 100% of the receivables due from Cardinal Health, with an additional $1.0 million deposited in a pledged collateral account by the Company as a bond. The $1.0 million previously deposited by the Company in the Court's registry as a bond will also be transferred to the pledged collateral account. CRG has filed a motion to dismiss the Company's cross-claims in Cardinal Health's interpleader action. The Company is in the process of responding to CRG's motion to dismiss.

The Company maintains that CRG's allegations of multiple events of default under the CRG Loan Agreement are without merit and the Company believes it has defenses against these claims. Furthermore, the Company believes that CRG's actions constitute a material breach of the CRG Loan Agreement and therefore, the Company is no longer subject to certain provisions of the CRG Loan Agreement. The Company believes that its best course of action is to pay off or refinance the CRG debt and pursue claims for damages. The Company is continuing to explore alternative financing arrangements, including the Proposed Transaction with Cardinal Health, in order to pay off or refinance the CRG debt. There can be no assurance that CRG will not prevail in exercising control over any additional banking arrangements that the Company creates, that the Company will be able to pay off or refinance the CRG debt or that the Company will be successful in its claims for damages. See Notes 2 and 9.

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. The Company intends to vigorously defend its position. In addition, the Company has filed counterclaims against Mr. Gonzalez. A three-person arbitration board has been chosen and a hearing is set for April 3-7, 2017 in Columbus, Ohio.

Former Director Litigation

On August 12, 2016, the Company commenced an action in the Superior Court of California for damages and injunctive relief against former Navidea Chairman and Macrophage Board Member Anton Gueth. The Complaint alleges, in part, that Mr. Gueth intentionally failed to disclose his prior existing relationship with CRG, in addition to multiple breaches including duty, loyalty and contract, interference and misappropriation. Litigation is currently stayed while the parties attempt to negotiate a settlement.

FTI Consulting, Inc. Litigation

On October 11, 2016, the Company was served with a Complaint filed in the Supreme Court of the State of New York, County of New York, alleging damages of at least $782,601.51 arising from investigative and consulting services that Plaintiff alleges it was retained by the Company to perform. The Company disputes the amount claimed to be due, as well as whether the services performed were properly authorized, and intends to vigorously defend the action.

11. Equity Instruments

During the nine-month period ended September 30, 2016, we issued 72,649 shares of our common stock valued at $56,609 to certain members of our Board of Directors who elected to receive stock in lieu of cash compensation.

12. Stock Warrants

At September 30, 2016, there are 11.7 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 $0.38 per share. The warrants have remaining outstanding terms ranging from 0.2 to 19 years.

In addition, at September 30, 2016, there are 300 warrants outstanding to purchase MT's Common Stock. The warrants are exercisable at $2,000 per share.

13. 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 September 30, 2016 and December 31, 2015.

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 September 30, 2016 or December 31, 2015 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 September 30, 2016, tax years 2012-2015 remained subject to examination by federal and state tax authorities.

14. Segments

We report information about our operating segments using the "management approach" in accordance with current accounting standards. This information is based on the way management organizes and reports the segments within the enterprise for making operating decisions and assessing performance. Our reportable segments are identified based on differences in products, services and markets served. There were no inter-segment sales. Prior to 2015, our products and development programs were all related to diagnostic substances. Our majority-owned subsidiary, Macrophage Therapeutics, Inc., was formed and received initial funding during the first quarter of 2015, which resulted in a re-evaluation of the Company's segment determination. We now manage our business based on two primary types of drug products: (i) diagnostic substances, including Lymphoseek 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 September 30, 2016	Diagnostics	Therapeutics	Corporate	Total
Lymphoseek sales revenue:				
United States (1)	$ 6,670,644	$ —	$ —	$ 6,670,644
International	19,446	—	—	19,446
Lymphoseek license revenue	1,295,625	—	—	1,295,625
Grant and other revenue	501,013	10,346	—	511,359
Total revenue	8,486,728	10,346	—	8,497,074
Cost of goods sold, excluding depreciation and amortization	909,539	—	—	909,539
Research and development expenses, excluding depreciation and amortization	1,028,389	247,664	—	1,276,053
Selling, general and administrative expenses, excluding depreciation and amortization (2)	839,410	27,758	1,974,419	2,841,587
Depreciation and amortization (3)	12,278	—	99,186	111,464
Income (loss) from operations (4)	5,697,112	(265,076)	(2,073,605)	3,358,431
Other income (expense), excluding equity in the loss of R-NAV, LLC (5)	—	—	(3,417,967)	(3,417,967)
Net income (loss)	5,697,112	(265,076)	(5,491,572)	(59,536)
Total assets, net of depreciation and amortization:				
United States	4,673,425	9,356	6,357,898	11,040,679
International	148,224	—	697	148,921
Capital expenditures	—	—	1,847	1,847

Three Months Ended September 30, 2015	Diagnostics	Therapeutics	Corporate	Total
Lymphoseek sales revenue:				
United States (1)	$ 2,942,498	$ —	$ —	$ 2,942,498
International	10,024	—	—	10,024
Lymphoseek license revenue	550,000	—	—	550,000
Grant and other revenue	476,755	—	—	476,755
Total revenue	3,979,277	—	—	3,979,277
Cost of goods sold, excluding depreciation and amortization	442,094	—	—	442,094
Research and development expenses, excluding depreciation and amortization	3,603,501	297,137	—	3,900,638
Selling, general and administrative expenses, excluding depreciation and amortization (2)	1,063,062	42,487	2,721,844	3,827,393
Depreciation and amortization (3)	17,013	—	115,216	132,229
Loss from operations (4)	(1,146,393)	(339,624)	(2,837,060)	(4,323,077)
Other income (expense), excluding equity in the loss of R-NAV, LLC (5)	—	—	(3,721,242)	(3,721,242)
Equity in the loss of R-NAV, LLC	—	—	(26,785)	(26,785)
Net loss	(1,146,393)	(339,624)	(6,585,087)	(8,071,104)
Total assets, net of depreciation and amortization:				
United States	3,750,702	—	13,291,939	17,042,641
International	440,349	—	467	440,816
Capital expenditures	—	—	2,788	2,788

Nine Months Ended September 30, 2016	Diagnostics	Therapeutics	Corporate	Total
Lymphoseek sales revenue:				
United States (1)	$ 14,660,670	$ —	$ —	$ 14,660,670
International	43,819	—	—	43,819
Lymphoseek license revenue	1,795,625	—	—	1,795,625
Grant and other revenue	2,052,197	61,798	—	2,113,995
Total revenue	18,552,311	61,798	—	18,614,109
Cost of goods sold, excluding depreciation and amortization	1,950,644	—	—	1,950,644
Research and development expenses, excluding depreciation and amortization	5,860,364	600,790	—	6,461,154
Selling, general and administrative expenses, excluding depreciation and amortization (2)	2,987,074	31,590	6,594,918	9,613,582
Depreciation and amortization (3)	66,842	—	311,992	378,834
Income (loss) from operations (4)	7,687,387	(570,582)	(6,906,910)	209,895
Other income (expense), excluding equity in the loss of R-NAV, LLC (5)	—	—	(10,621,828)	(10,621,828)
Equity in the loss of R-NAV, LLC	—	—	(15,159)	(15,159)
Net income (loss)	7,687,387	(570,582)	(17,543,897)	(10,427,092)
Total assets, net of depreciation and amortization:				
United States	4,673,425	9,356	6,357,898	11,040,679
International	148,224	—	697	148,921
Capital expenditures	—	—	1,847	1,847

Nine Months Ended September 30, 2015	Diagnostics	Therapeutics	Corporate	Total
Lymphoseek sales revenue:				
United States (1)	$ 6,736,418	$ —	$ —	$ 6,736,418
International	15,074	—	—	15,074
Lymphoseek license revenue	883,333	—	—	883,333
Grant and other revenue	1,320,816	—	—	1,320,816
Total revenue	8,955,641	—	—	8,955,641
Cost of goods sold, excluding depreciation and amortization	1,167,141	—	—	1,167,141
Research and development expenses, excluding depreciation and amortization	9,610,012	559,888	—	10,169,900
Selling, general and administrative expenses, excluding depreciation and amortization (2)	4,634,279	120,872	8,381,910	13,137,061
Depreciation and amortization (3)	207,498	—	223,870	431,368
Loss from operations (4)	(6,663,289)	(680,760)	(8,605,780)	(15,949,829)
Other income (expense), excluding equity in the loss of R-NAV, LLC (5)	—	—	(8,808,202)	(8,808,202)
Equity in the loss of R-NAV, LLC	—	—	(295,217)	(295,217)
Net loss	(6,663,289)	(680,760)	(17,709,199)	(25,053,248)
Total assets, net of depreciation and amortization:				
United States	3,750,702	—	13,291,939	17,042,641
International	440,349	—	467	440,816
Capital expenditures	25,492	—	4,914	30,406

(1) All sales to Cardinal Health are made in the United States; Cardinal distributes the product throughout the U.S. through its network of nuclear pharmacies.

(2) 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. Marketing and selling expenses are allocated to our individual reportable segments.

(3) Depreciation and amortization is reflected in cost of goods sold ($12,278 and $15,496 for the three-month periods ended September 30, 2016 and 2015, and $66,842 and $72,237 for the nine-month periods ended September 30, 2016 and 2015), research and development ($0 and $1,517 for the three-month periods ended September 30, 2016 and 2015, and $0 and $10,617 for the nine-month periods ended September 30, 2016 and 2015), and selling, general and administrative expenses ($99,186 and $115,216 for the three-month periods ended September 30, 2016 and 2015, and $311,992 and $348,514 for the nine-month periods ended September 30, 2016 and 2015).

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

(5) Amounts consist primarily of interest income, interest expense, changes in fair value of financial instruments, and losses on debt extinguishment, which are not currently allocated to our individual reportable segments.

15. Supplemental Disclosure for Statements of Cash Flows

During the nine-month periods ended September 30, 2016 and 2015, we paid interest aggregating $4.2 million and $3.3 million, respectively. Interest paid during the nine-month period ended September 30, 2016 includes collection fees of $778,000 and a prepayment premium of $2.1 million, both of which were withdrawn by CRG from a bank account under their control. During the nine month-period ended September 30, 2015, we recorded $1.0 million of end-of-term fees associated with our notes payable to CRG. During the nine-month periods ended September 30, 2016 and 2015, we issued 67,002 and 68,157 shares of our common stock as matching contributions to our 401(k) Plan which were valued at $120,800 and $117,099, respectively.

16. Subsequent Events

a. CRG Litigation: CRG's objection to the supersedeas was heard on October 31, 2016, during which the Texas court ruled that an additional $500,000 should be placed in the pledged collateral account within ten days of the ruling.

Also in October 2016, a revised temporary restraining order was issued by the Ohio court, allowing the Company to receive 100% of the receivables due from Cardinal Health, with an additional $1.0 million deposited in the pledged collateral account by the Company as a bond. Further, the Ohio court ruled that the Company remain current on its quarterly interest payments to CRG. On October 7, 2016 the Company paid $1.3 million to CRG to cover the third quarter 2016 interest payment. The $1.0 million previously deposited by Cardinal Health in the Court's registry as a bond will also be transferred to the pledged collateral account.

b. FTI Consulting, Inc. Litigation: On October 11, 2016, the Company was served with a Complaint filed in the Supreme Court of the State of New York, County of New York, alleging damages of at least $782,601.51 arising from investigative and consulting services that Plaintiff alleges it was retained by the Company to perform. The Company disputes the amount claimed to be due, as well as whether the services performed were properly authorized, and intends to vigorously defend the action.

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, negative net worth and uncertainty of future profitability;
- our ability to repay our debts;
- the outcome of the CRG litigation;
- our ability to successfully complete research and further development of our drug candidates;
- the timing, cost and uncertainty of obtaining regulatory approvals of our drug candidates;
- our ability to successfully commercialize our drug candidates;
- our 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 help identify the sites and pathways of undetected disease and enable better diagnostic accuracy, clinical decision-making, targeted treatment and, ultimately, patient care.

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. Lymphoseek is a novel, state-of-the-art, receptor-targeted, small-molecule radiopharmaceutical used in the evaluation of lymphatic basins that may have cancer involvement in patients. Lymphoseek is designed for the precise identification of lymph nodes that drain from a primary tumor, which have the highest probability of harboring cancer. Lymphoseek is approved by the U.S. Food and Drug Administration (FDA) for use in solid tumor cancers where lymphatic mapping is a component of surgical management and for guiding sentinel lymph node biopsy in patients with clinically node negative breast cancer, melanoma or squamous cell carcinoma of the oral cavity.

On September 5, 2016, the Company entered into a non-binding letter of intent (LOI) with Cardinal Health pursuant to which Cardinal Health intends to acquire the Company's Lymphoseek product (the Product) and certain intellectual property rights and other assets related to the Product (the Acquired Assets) and assume certain liabilities associated with the Acquired Assets (the Proposed Transaction). The purchase price for the Proposed Transaction shall consist of (i) $80 million in cash payable at closing (reduced to the extent the amount of transferred Product inventory is less than $6 million), plus (ii) annual earn-out and milestone payments based upon the volume of Product sales. For the first three years, the earn-out payments shall be no less than $6.7 million per year. In no event will the entire purchase price, including all earn-out payments, exceed $310 million.

As part of the Proposed Transaction, the parties have agreed that simultaneous with the closing, subject to certain conditions, Cardinal Health will license to the Company (License Back), on a perpetual royalty free basis, certain rights to the Acquired Assets necessary for the Company to (i) develop, manufacture, market, sell and distribute new pharmaceutical and other products on an exclusive basis so long as such products do not compete with the Product, and (ii) manufacture, market, sell and distribute the Product throughout the world other than in North America on a non-exclusive basis.

Also as part of the Proposed Transaction, the Company shall grant to Cardinal Health five (5) year warrants to purchase up to 10 million shares of the Company's common stock, par value $.001 per share, at an exercise price of $1.50 per share and provide Cardinal Health with a right of first offer related to the assets covered by the License Back and new products developed by the Company in certain circumstances during the life of the Product's patents.

The parties intend to negotiate and execute definitive agreements for the Proposed Transaction with customary provisions for a transaction of this size and scope, including representations and warranties regarding the Company, its business, and the Acquired Assets, indemnification of Cardinal Health by the Company, covenants and closing conditions. The closing of the Proposed Transaction is subject to, among other things, the satisfactory completion of due diligence by Cardinal Health and approval of the Company's stockholders.

Unless written notice is given to the Company that Cardinal Health is ceasing further discussions related to the Proposed Transaction, the Company has agreed not to initiate or enter into any discussions with any third party regarding a possible sale of any equity or material assets of the Company or its subsidiaries for a period of thirty days from the date of the LOI. If the Company does not consummate a transaction with Cardinal Health as contemplated by the LOI and at any time within 180 days of the date of the LOI consummates one or more transactions that, directly or indirectly, result in a sale, license or other transfer of the Product, or all or substantially all of the Company's assets, then a certain Supply and Distribution Agreement between the Company and Cardinal Health shall automatically be extended for an additional three-year period. The parties have agreed that the provisions described in this paragraph shall be binding.

Lymphoseek has also received European approval in imaging and intraoperative detection of sentinel lymph nodes in patients with melanoma, breast cancer or localized squamous cell carcinoma of the oral cavity.

Building on the success of Lymphoseek, the flexible and versatile Manocept platform acts as an engine for the design of purpose-built molecules offering the potential to be utilized across a range of diagnostic modalities, including single photon emission computed tomography (SPECT), positron emission tomography (PET), intra-operative and/or optical-fluorescence detection in a variety of disease states.

Recent preclinical data generated by the Company in studies using tilmanocept linked to a therapeutic agent also suggest that tilmanocept's binding affinity to CD206 receptors demonstrates 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, cardiovascular, and central nervous system diseases. Our efforts in this area were further supported by the January 2015 formation of Macrophage Therapeutics, Inc., a majority-owned subsidiary that was formed specifically to further explore immuno-therapeutic applications for the Manocept platform.

Our focus on development of our proprietary Manocept platform technology further supports the 2014 decision by the Company's Board of Directors to reduce our support for, while seeking to partner or out-license, our two neurological development programs, NAV4694 and NAV5001.

Other than Lymphoseek, 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 our now-approved Lymphoseek product, as well as other diagnostic and therapeutic line extensions based on our Manocept platform, while we have sought to partner or divest our two neuro-imaging product candidates. Efforts to partner or divest NAV4694 are still active, while the in-license of NAV5001 we had with Alseres was terminated in April 2015.

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. In particular, substantial progress on the Manocept platform has resulted in several promising opportunities, including the formation of Macrophage Therapeutics, Inc. in January 2015. Additionally, in September 2016 the Company entered into a LOI with Cardinal Health that, if closed successfully, will significantly improve our financial condition and our ability to continue as a going concern.

Navidea has been awarded several Small Business Innovation Research (SBIR) and other grants to partially fund clinical trials to increase medical adoption of Lymphoseek in other solid tumors and development activities supporting other immuno-diagnostic applications through Phase 1/2 studies and the first grant to support development of an immunotherapeutic application in Kaposi's sarcoma (KS).

Lymphoseek - Regulatory Background

Lymphoseek is a lymph node targeting radiopharmaceutical agent intended for use in intraoperative lymphatic mapping procedures and lymphoscintigraphy employed in the overall diagnostic assessment of certain solid tumor cancers. Lymphoseek has the potential to provide oncology surgeons with information to identify key predictive lymph nodes that may harbor cancer and to help avoid the unnecessary removal of non-cancerous lymph nodes and the surrounding tissue in patients with a variety of solid tumor cancers. Lymphoseek was approved and indicated for use in lymphatic mapping for breast cancer and melanoma by the FDA in March 2013. In June 2014, the FDA approved a supplemental New Drug Application (sNDA) for the expanded use of Lymphoseek indicated for guiding sentinel lymph node biopsy in head and neck cancer patients with squamous cell carcinoma of the oral cavity. In September 2014, the FDA granted Orphan Drug Designation for use in sentinel lymph node detection in patients with cancer of the head and neck. This designation provides for a seven-year market exclusivity period in this indication as well as certain incentives, including federal grants, tax credits and a waiver of filing fees. In October 2014, the FDA approved a second sNDA for lymphatic mapping in solid tumors and added sentinel lymph node detection for breast cancer and melanoma to the approved indications. The FDA also allowed expanded utilization of Lymphoseek with or without scintigraphic imaging, known as lymphoscintigraphy, to enable pre-operative imaging and mapping of lymph nodes to facilitate node localization during surgical procedures. Lymphoseek is now the first and only FDA-approved radiopharmaceutical agent for sentinel lymph node detection and is the only FDA-approved agent for lymphatic mapping of solid tumors. Additional trials, including pediatric studies and trials in anal/rectal, endometrial, and cervical cancers, and others in various stages of execution, planning or consideration, are anticipated to provide additional data to potentially support greater medical adoption and expansion of the Lymphoseek opportunity.

We submitted our Marketing Authorization Application (MAA) for Lymphoseek to the European Medicines Agency (EMA) in December 2012. In September 2014, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending marketing authorization for Lymphoseek for use in the EU 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. The CHMP's positive opinion was reviewed by the European Commission (EC), which has the authority to approve medicinal products for use in the 28 countries of the EU and generally follows the recommendations of the CHMP. The EC granted marketing authorization for Lymphoseek 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 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 fourth quarter of 2016.

Lymphoseek – Ongoing Clinical Data and Licensing Background

In January 2016, we announced that the first pediatric patient was enrolled in a clinical study comparing Lymphoseek and vital blue dye (VBD) in a pediatric population of patients with melanoma, rhabdomyosarcoma, or other solid tumors. The study is designed to investigate how Lymphoseek compares with VBD in identifying lymph nodes as well as evaluate safety and tolerability in the pediatric population. Lymphoseek is currently approved for adult use only. Enrollment is currently planned at approximately six sites throughout the U.S. The first patient was enrolled by Jennifer Aldrink, M.D., Assistant Professor of Clinical Surgery at The Ohio State University College of Medicine and Director of Surgical Oncology, Division of Pediatric Surgery at Nationwide Children's Hospital in Columbus, Ohio. Primary goals of this prospective, open-label, multicenter study are to evaluate safety and tolerability of Lymphoseek in this subject population and determine the concordance of in vivo detection rates of Lymphoseek and of VBD in tissue excised and histologically confirmed as lymph nodes. In addition, the study is designed to measure other efficacy signals including assessment of the identified lymph node(s) to confirm: the presence/absence of tumor metastases; agent localization per tumor type; degree of localization (nodes per subject both intraoperatively and with preoperative SPECT/CT); reverse concordance parameters; change of subject stage based on histopathology and descriptive assessment on change in treatment plan; and number of lymph nodes detected with Lymphoseek intraoperatively compared with preoperative SPECT/CT imaging.

In February 2016, we announced enrollment of the first patient in a clinical study evaluating Lymphoseek in women with known cervical cancer. The study, funded in part by a Fast Track SBIR grant from the National Institutes of Health (NIH), will assess the use of Lymphoseek in sentinel lymph node biopsy during cervical cancer surgery in support of the existing Lymphoseek label in lymphatic mapping. Enrollment is currently planned in up to six sites throughout the U.S. The first patient was enrolled by Michael M. Frumovitz, M.D., M.P.H., Associate Professor, Department of Gynecologic Oncology and Reproductive Medicine, principal investigator at The University of Texas MD Anderson Cancer Center. This multi-center, prospective, open-label study intends to enroll up to 40 women with International Federation of Gynecology and Obstetrics IA2-IIA1 staging. Subjects will receive a single dose of Lymphoseek administered peritumorally approximately 1-2 hours before surgery. The results are expected to report per-patient false negative rates and compare the pathology status of Lymphoseek-identified sentinel lymph nodes relative to the pathology status of non-sentinel lymph nodes in nodal staging of patients. Additionally, the study is expected to report sensitivity, negative predictive value, and accuracy.

In June 2016, we announced results from three investigator-initiated studies that demonstrate beneficial performance characteristics of Lymphoseek and positive comparative results versus commonly-used, non-receptor-targeted imaging agents. The data were presented by the investigators at the 2016 Annual Meeting of the Society of Nuclear Medicine and Molecular Imaging (SNMMI) in San Diego, CA.

In the presentation entitled, "*Performance of Tc-99m tilmanocept when used alone is as or more effective in localizing sentinel nodes than sulfur colloid plus blue dye*," Jonathan Unkart and Anne Wallace, M.D., Department of Surgery at the University of California San Diego (UCSD), described a retrospective evaluation of the rate of localization of Lymphoseek when used alone compared to sulfur colloid (SC), blue dye (BD) and SC plus BD. The study included results from 148 breast cancer patients evaluated in two prospective Phase 3 Lymphoseek clinical trials (data published in Annuls of Surgical Oncology 2013). SC and BD data was derived from a literature search presented at the SNMMI 2013 Annual Meeting including treatment groups of 17,814 SC alone, 12,821 BD alone and 19,627 SC+BD patients. Results show the following localization rates: Lymphoseek alone: 0.9865, SC alone: 0.9249, BD alone: 0.8294 and SC+BD: 0.9636. The authors' analysis suggests that Lymphoseek provided superior sentinel lymph node localization in breast cancer patients compared to the other non-targeting agents alone or in combination providing surgeons the option to use just a single agent.

The presentation, "*Use of lymphoscintigraphy with Tc-99m tilmanocept does not affect the number of nodes removed during sentinel node biopsy (SLNB) in breast cancer*," also presented by Dr. Unkart, shows data from a retrospective review evaluating whether there is a difference in the number of nodes removed using Lymphoseek during SLNB in patients who had a pre-operative imaging procedure called lymphoscintigraphy prior to SLNB versus those who only had intra-operative sentinel node (SN) identification. The results indicate that in breast cancer, identification and removal of SNs using lymphoscintigraphy (3.0 SNs) did not significantly alter the number of SNs removed during a SLNB procedure with no imaging (2.7 SNs). Lymphoseek's selective-targeting performance characteristic enables the utilization of only a single dose of Lymphoseek per patient irrespective of whether both lymphoscintigraphy and SLNB are performed. The authors concluded that by using Lymphoseek, lymphoscintigraphy imaging procedures may be eliminated in this patient population and may reduce health care cost without impacting patient outcomes.

The presentation entitled, "*Rate of sentinel lymph node visualization in fatty breasts: Tc-99m Tilmanocept versus Tc-99m filtered sulfur colloid*," describes results from a study at Emory University School of Medicine using Lymphoseek in patients with fatty breast tissue, a population that is known to be more difficult to localize nodes when performing SLNB. The results suggest that Lymphoseek more effectively visualized sentinel lymph nodes (SLNs) both on lymphoscintigraphy and during surgery compared to filtered sulfur colloids (Tc-SC) with 100% localization using Lymphoseek intraoperatively. Dr. Maryam Shahrzad, M.D. presented retrospective data compiled from 29 consecutive patients with early stage breast cancer where lymphoscintigraphy was performed using Tc-SC and 28 patients where lymphoscintigraphy was performed using Lymphoseek. Multiple patient variables were recorded. The Tc-SC cohort included 96% of patients with fatty breasts versus 89% in the Lymphoseek group. Statistically significant findings included: (1) in lymphoscintigraphy, SLN visualization occurred in 86% of the Lymphoseek group compared to 59% of the TC-SC group (*p-value: 0.02*); and (2) at surgery, 100% of patients in the Lymphoseek group showed a "hot" SLN compared to only 79% of patients in the Tc-SC group (*p-value: 0.01*).

These data further reinforce the beneficial clinical performance attributes of Lymphoseek. In addition, they support Lymphoseek's rapid adoption in sentinel lymph node biopsy procedures and its pre-surgical imaging utility for other solid tumors. We believe results from these and other performance-based studies will encourage surgeons to use Lymphoseek as they look to optimize outcome for their patients and improve patient experience.

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, 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 Company's FDA-approved sentinel node/lymphatic mapping agent, Lymphoseek, 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 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 rheumatoid arthritis (RA), atherosclerosis/vulnerable plaque, Crohn's disease, systemic lupus erythematosis, KS, and others that span clinical areas in oncology, autoimmunity, infectious diseases, cardiology, central nervous system (CNS) diseases, and inflammation. Data from studies using agents from the Manocept platform in RA, KS and tuberculosis (TB) were published in a special supplement, *Nature Outlook: Medical Imaging*, in *Nature's* October 31, 2013 issue. The supplement included a White Paper by Navidea entitled "*Innovations in receptor-targeted precision imaging at Navidea: Diagnosis up close and personal*," focused on the Manocept platform.

Manocept Platform – Immuno-Diagnostics Clinical Data

In April 2016, we announced that based on a meeting with the FDA, we will begin the clinical trial development process for our intravenous (IV) injection protocols for use of tilmanocept in RA and other disease states. Over the past year Navidea conducted a series of meetings and communications with the FDA to gain clarity on a path to extend the current Lymphoseek investigational new drug (IND) application to support IV administration of tilmanocept. In parallel, the Company initiated its clinical development efforts and has already completed six required non-clinical animal studies for this new route of administration, submitted the summary results in a briefing package to the FDA, and secured NIH grants in RA and KS, worth up to $3.8 million to support further development through Phase 2 studies. Based upon the feedback from the latest meeting, Navidea expects to submit an IND amendment to the FDA that will allow initiation of Phase 1/2 IV studies of tilmanocept. The addition of this new route of administration would enable further development of tilmanocept in broader immunodiagnostic disease applications including RA and KS.

Rheumatoid Arthritis

Our efforts to exploit the involvement of macrophages in the natural history of many diseases has led us through our strategy of expanding the use of tilmanocept and open new market opportunities. Importantly, one of the largest defined market opportunities resides in early diagnosis and disease monitoring for rheumatoid arthritis or RA. RA can be hard to detect because it may begin with subtle symptoms such as achy joints or joint stiffness especially in the morning. Also, many diseases behave like RA early on; for example, gout and lupus. There is no single test that confirms an RA diagnosis. Current diagnostic tools such as x-rays, ultrasound and MRI are reasonable, but still fall short of being able to quantitatively measure inflammation and the underlying macrophage inflammatory component, which is a key driver of RA progression. Misdiagnosis results in billions of dollars being spent each year unnecessarily on therapies, which may also result in significant side effects.

In our primary market research, two aspects of the current unmet medical needs identified were early diagnosis and monitoring of disease progression and/or drug response. Early diagnosis and treatment improves outcomes. In patients with RA, joint damage occurs early, often within the first two years of the disease, and is irreversible. Additionally, once treatment is started, it becomes necessary to objectively monitor progression and measure how well a treatment is working or not.

Approximately 10 million patients in economically advantaged countries alone are diagnosed with RA, of which approximately half are misdiagnosed due in large part to a lack of an accurate and cost-effective means for early detection and differential diagnosis. Drilling further down, our primary market research suggests that early detection alone in the U.S. could add up to 300,000 procedures per year and disease monitoring could add up to another 700,000 procedures per year.

Our goals for the use of tilmanocept in RA are:

- reliable diagnosis of RA by imaging;
- early differential diagnosis of RA; and
- use in monitoring patient response to RA treatments.

Based on our preliminary work, we believe we can achieve all three diagnostic disease-managing elements with tilmanocept.

In June 2015, results from several pre-clinical Manocept studies in RA were presented at the EULAR 2015 European Congress of Rheumatology. The results of the studies, led by Wael Jarjour, M.D. and Thomas J. Rosol, D.V.M., Ph.D., of The Ohio State University Wexner Medical Center and College of Veterinary Medicine, respectively, highlighted the potential of CD206-targeting Manocept constructs to detect immune-mediated inflammation in RA which could be used diagnostically, to monitor therapeutic efficacy, or as a potential therapeutic platform. The presentation showed results from synovial fluid and tissue acquired from RA patients for comparison to normal frozen archival tissue and synovial tissue procured from patients with osteoarthritis (OA). Tissues were probed with Manocept-Cy3, DAPI nuclear stain, and anti CD206-cyanine. Mononuclear cells were isolated from RA synovial fluid and analyzed by flow cytometry. Results demonstrated that archival synovial tissue and synovial fluid obtained from patients diagnosed with RA contain a significant population of macrophages that express high levels of the CD206 receptor. It was shown that these macrophages strongly co-localize Manocept-Cy3 and CD206 receptors. The degree of macrophage infiltration in tissue from healthy or osteoarthritic patients was significantly lower than in RA tissues. Additionally, in an *in-vivo* animal study, arthritis was induced in mice and was followed with intravenous injection of Manocept-Cy3 and epi-fluorescent imaging. Imaging results indicated that Manocept can be detected in inflamed joints in an in vivo animal model of RA.

In July 2015, we received an initial notice of award for a Fast Track SBIR grant from the NIH's National Institute of Arthritis and Musculoskeletal and Skin Diseases, to fund preclinical animal studies and a Phase 1/2 human clinical study examining the ability of Tc 99m tilmanocept to identify skeletal joints that are inflamed due to RA. RA is a chronic, progressive, systemic autoimmune disease characterized by inflammation of numerous skeletal joints. If not treated successfully, RA can lead to disability, disfigurement and premature death. The funds for this Fast Track grant were released in two parts, which together provide a total of $1.4 million in resources over two and a half years to achieve the specific aims and objectives of the grant. The first part provided $225,000 to support preclinical animal studies and to support activities needed to prepare for the Phase 1/2 clinical study. In July 2016, we

received notification of award of the second part of the grant for an additional $1.1 million that will support the Phase 1/2 study, the results of which are expected to confirm the safety and effectiveness of Tc 99m tilmanocept to identify skeletal joint inflammation due to RA.

In July 2016, we received Institutional Review Board (IRB) approval from the University of California, San Francisco (UCSF) School of Medicine for a clinical study examining the ability of tilmanocept to specifically identify active RA in pre-identified RA-affected joints. Additionally, Navidea has received Western Institutional Review Board (WIRB) approval to expand this study to other study sites at Navidea's discretion. This study has been designed as an open-label, Phase 1 clinical study of up to 18 individuals to investigate the ability of a subcutaneous injection of Tc 99m-tilmanocept to identify RA inflamed joints in active RA subjects by SPECT and SPECT/CT imaging. The study will enroll four cohorts of subjects: participants with active RA and arthritis-free individuals evaluating two different tilmanocept doses in each group. Results of this study will be used to determine tilmanocept's ability to localize in subjects with RA and show concordance with clinical symptoms, compare the intensity between the two dose groups, and compare localization between active RA and arthritis-free subjects. Study results will help to inform the trial design for follow-on studies. Two study sites are now open for enrollment and 17 or 18 subjects have been dosed and imaged.

In conjunction with the agreed submission of an IND amendment for IV administration of tilmanocept to the FDA, we expect to initiate 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 before the end of 2016.

Cardiovascular Disease

In July 2015, we received a notice of award for a Phase 1 SBIR grant providing $322,000 from the National Heart Lung and Blood Institute, NIH. The study, currently ongoing in collaboration with Massachusetts General Hospital and Harvard Medical School, will examine the ability of Tc 99m tilmanocept to localize in high-risk atherosclerotic plaques. These specific plaques are rich in CD206 expressing macrophages and are at high risk for near term rupture resulting in myocardial infarctions, sudden cardiac death and strokes. The consequences of atherosclerosis and the cardiovascular disease that atherosclerosis causes, while severe in all populations of people, are particularly concentrated in human immunodeficiency virus (HIV)+ patients. Recently, it has been observed that CD206 expressing macrophages densely populate vulnerable plaques or thin cap fibroatheromas but not other kinds (i.e., calcified plaques) of atherosclerotic plaques. A primary goal for this grant involves an approved clinical investigation of up to 18 individuals with and without aortic and high risk coronary atherosclerotic plaques and with and without HIV infection to determine the feasibility of Tc 99m tilmanocept to image high risk plaque by SPECT/CT. Contrast with NaF18 is a parallel evaluation. Results have the potential to provide 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 each group, 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.

In May 2016, we reported that the first subjects were dosed subcutaneously at Massachusetts General Hospital, and we have now completed enrollment in this study. Results are being analyzed and a manuscript has been submitted for publication.

Other Immuno-Diagnostic Applications

In July 2015, imaging results from the Manocept clinical trial in KS and other preclinical studies were presented at the 18th International Workshop on Kaposi's Sarcoma Herpesvirus (KSHV) and Related Agents. The clinical imaging study, using Tc 99m tilmanocept in both HIV+ and HIV- patients suggests that KS tumor lesions, both cutaneous and suspected extra-cutaneous sites, can be easily visualized and mapped, demonstrating that this technique may potentially provide a means for routine patient assessment. The results also demonstrate that use of Manocept represents a potential therapeutic pathway for targeting tumor-associated macrophages (TAMs). Manocept agents are designed to target CD206, which is highly expressed on TAMs and the KS tumor itself. As a potential therapeutic, Manocept could be used as a precision vehicle to deliver payloads to tumor sites throughout the body. Five Human Herpes Virus8 positive (HHV8+) patients (4 HIV+, 1HIV-) were enrolled in the NAV3-12 study. Patients received a single subcutaneous injection of Tc 99m tilmanocept in the region of a cutaneous KS lesion and imaging was performed at 1, 4 and 24 hours post-injection to visualize localization of tilmanocept. Results represented by whole body SPECT/CT imaging scans from study patients were presented. Collectively, the scans show localization of tilmanocept specifically in KS and detected multiple cutaneous lesions in the extremities, as well as extra-cutaneous localization found in the nasopharynx, lymph nodes and brain. Results also indicate that KS lesions are anatomically linked in chains by and within the lymph ducts. The study concludes that both HIV+ and HIV- patients have pan-tumor expression of CD206, strongly suggests tilmanocept crosses the blood-brain barrier and that a Manocept-drug conjugate may have the potential as a therapeutic with high target effect and low off-target concerns. The data from these studies also suggest a novel theory on the genesis of KS in which KS arises from an HHV8 infected macrophage type cell and its interaction with the lymphatic system. This interaction provides the means for access of the KS through CD206 receptor for diagnosis, evaluation, and potential therapy using the Manocept platform.

In September 2015, we received an initial notice of 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.

Over the course of the last few years, management has provided periodic updates regarding the status of the NAV1800 development program we previously referred to as the RIGS® (radioimmunoguided surgery) program. During that time, our commercial evaluation of new clinical data caused us to question the viability of the monoclonal antibody initiative as it was originally envisioned, and we learned significantly more about tilmanocept, the underlying Manocept backbone, and the potential utility of tilmanocept in identifying TAMs, and their consequent potential utility in identifying multifocal tumor disease itself. To that end, we petitioned the NIH to repurpose the $1.5 million grant we were previously awarded towards the study of TAMs in colorectal cancer, and subsequently received confirmation of the acceptance of this repurposing. This repurposed grant now supports a Manocept-based diagnostic approach in patients with anal/rectal cancer and possibly colon cancer. We recognize this repurposing represents a major refocusing of the original NAV1800 initiative, but we are confident that this change represents the best course of action at this time towards benefiting patients afflicted with colorectal cancer and is one which is consistent with the excitement we are seeing on many fronts related to our work on the Manocept platform. However, there can be no assurance that if further clinical trials for this product proceed, that they will be successful, that the product will achieve regulatory approval, or if approved, that it will achieve market acceptance.

Macrophage Therapeutics Background

In January 2015, Navidea formed Macrophage Therapeutics, Inc. (MT), a majority-owned subsidiary that was formed specifically to further explore immune-therapeutic applications for the Manocept platform.

In February 2015, Navidea announced the appointment of leading experts to a newly formed scientific advisory board (SAB) to serve as a strategic resource to MT as MT looks to develop therapeutic applications for Navidea's Manocept platform. The inaugural SAB consortium is comprised of world-renowned scientists and clinicians in the areas of oncology, immunology, autoimmune diseases and macrophage biology. The SAB will serve as an ongoing resource to provide counsel and guidance pertaining to the research, development, and clinical use of our Manocept technology in therapeutic applications.

In September 2015, MT announced that it had developed preliminary processes for producing the first two therapeutic Manocept immunoconstructs, MT-1001, designed to specifically target and kill activated CD206+ macrophages and MT-2001, designed to inhibit the inflammatory activity of activated CD206+ macrophages. These constructs are the result of the activities of Navidea's clinical development and research group. MT-1001 and MT-2001 were developed from the Manocept platform technology and the efforts of Navidea's development team and contain a similar chemical scaffold and targeting moieties designed to selectively target CD206+ macrophages. A payload of a therapeutic molecule is conjugated to each immunoconstruct through a linkage that will release the molecule within the targeted tissue: MT-1001 has doxorubicin, an anthracycline antitumor agent, conjugated to the Manocept backbone and MT-2001 has a potent anti-inflammatory agent conjugated to it. MT has contracted with an independent facility to produce sufficient quantities of MT-1001 and MT-2001 along with the concomitant analytical standards, to provide material for planned preclinical animal studies.

Manocept Platform – Immunotherapeutics Clinical Data

In March 2015, Navidea and MT announced that data from an ongoing human study indicated that the Manocept technology platform appears to have the ability to safely cross the blood brain barrier without losing its ability to deliver its payload to the intended target. Based on these data and on the advice of the Company's SAB, MT hopes to expand the SAB to include members with specific expertise in CNS diseases. The blood brain barrier has proven to be a significant obstacle to treating many diseases of the central nervous system. In an imaging study using the Manocept targeted delivery system, foci on the other side of the blood brain barrier were observed that strongly and specifically localized tilmanocept. Many of the leading diseases of the central nervous system such as Alzheimer's and Parkinson's diseases as well as autoimmune CNS diseases such as multiple sclerosis and ALS have pathologies that can in part be attributed to over-active macrophages, the target for Manocept delivery technology.

In July 2015, Navidea and MT announced that preclinical results in KS demonstrated that a cytotoxic drug, doxorubicin, linked to Manocept was targeted to and dose-dependently taken up in CD206+ KS tumor cells and TAMs and caused apoptotic death of the KS tumor cells and TAMs. The results were presented at the 18th International Workshop on KSHV and Related Agents by Michael S. McGrath, M.D., Ph.D., Professor, Departments of Laboratory Medicine, Pathology, and Medicine at UCSF. The study also shows that Cy3-Manocept and a Cy3-Manocept-doxorubicin conjugate quantitatively permitted the evaluation of tumor burden, tissue uptake of Manocept and tumor response to therapy *in vitro* and *ex vivo*, supporting the potential for the Manocept platform to be used not only diagnostically but as a precision targeted molecule to deliver payloads to tumor sites throughout the body. In summary, the data presented include evidence that:

- KS tissue based cells take up Cy3-Manocept or Cy3-Manocept-doxorubicin into both KS tumor cells and TAMs.
- Manocept conjugate uptake is dose and time dependent in CD206+ macrophages.
- Cy3-Manocept and Cy3-Manocept-doxorubicin bind to CD206 positive macrophages equivalently indicating that the linkage of a drug conjugate did not lessen the CD206 binding ability.
- Manocept-doxorubicin killed CD206 expressing macrophages. After 24 hours, Cy3-Manocept-doxorubicin killed 70% of CD206 positive macrophages in tissue cultures. Doxorubicin alone showed no toxicity.
- KS organ culture treated with Manocept-doxorubicin resulted in the loss of macrophages and induced programmed tumor cell death and apoptosis in KS HHV8+ spindle cells, and showed anti-HIV activity in HIV infected macrophage cultures.

During investor update conference calls held in the second quarter of 2016, MT reported the following from its ongoing pre-clinical animal studies:

- An 8-week, preclinical mouse study in an arthritis mouse model with a Manocept anti-inflammatory targeted therapeutic product, MT2002, was completed with initial results reporting clear anti-inflammatory activity with no apparent significant side-effects;
- An animal study in an asthma model that measured the ability of MT2002 to decrease all three markers of pro-inflammatory markers secreted by disease-causing macrophages was completed and successfully demonstrated an anti-inflammatory effect;
- Two studies using a neuro-inflammation model and an animal model for nonalcoholic steatohepatitis (NASH) completed animal dosing with results expected in the coming weeks;
- A number of studies were initiated evaluating the performance of compounds from the MT1000 class of compounds designed to deplete TAMs in a number of different cancer models.

Further updates include the following:

- We completed the dosing for the study in an animal model for NASH. Using a non-optimized agent and a non-optimized dosing regimen, promising results were noted that show the MT compound was effective. In addition, the livers of these animals were analyzed and showed no evidence of clinical or histo-pathological damage. Based on these findings the outside investors in MT have agreed to fund a larger and longer-term study to advance development of the data set in NASH.
- We completed dosing in a neuro-inflammation model which confirmed that the anti-inflammatory construct very effectively crosses the blood-brain barrier. This study also confirmed that the addition of the drug conjugate to the Manocept backbone did not affect blood-brain barrier activity.
- We completed two studies evaluating the performance of compounds from the MT1000 class of compounds designed to deplete TAMS in a number of different cancer models. In both models studied to date, we saw an immediate effect on the rate of tumor growth. In the slower growing tumor model, we saw that the inhibition in tumor growth rate remained throughout the duration of the study. Histology evaluation of the tumor is being conducted to determine what effect the compound had on the tumor itself.

In May 2016, Navidea and MT announced the receipt of an initial notice of award for a Fast Track SBIR grant providing for up to $1.8 million from the NIH's National Cancer Institute (NCI) to fund evaluation of an investigational Manocept-based immunotargeted treatment for KS. The novel Manocept construct is designed to specifically deliver doxorubicin, a chemotoxin, which can kill KS tumor cells and their TAMs 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 (MT1000 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 and RA. 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.

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 Lymphoseek 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 (see Part II, Item 1 – Legal Proceedings). 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.

In July 2016, the Company executed a term sheet with Cerveau Technologies, Inc. (Cerveau) as a designated party for the rights resulting from the relationship between Navidea and Sinotau. The term sheet outlined the terms of a potential agreement between the parties to sublicense NAV4694 to Cerveau in return for license fees, milestone payments and royalties. With the exception of certain provisions, the term sheet was non-binding and was subject to the agreement of AstraZeneca, from whom the Company has licensed the NAV4694 technology. The Company had 60 days to execute a definitive agreement, however no definitive agreement was reached. Discussions related to the potential partnering or divestiture of NAV4694 are ongoing.

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. As of the filing of this document, we remain in discussions and Alseres has expressed its commitment to pay the related payables.

Outlook

Following the U.S. approval of Lymphoseek in March 2013, the Company undertook the initial stages of product launch in the U.S. with our commercialization partner, Cardinal Health, in May 2013. In October 2014, we received approval from FDA for a significantly expanded product label for Lymphoseek. During the second quarter of 2015, we successfully deployed Navidea's direct sales personnel as part of our effort to accelerate Lymphoseek revenue growth in the remainder of 2015 and beyond. Our strategy for increasing Lymphoseek revenue focused on a new brand strategy reflective of the expanded product label that allows the delivery of a compelling clinical value proposition message targeting the oncology treatment team including surgical oncologists and nuclear medicine physicians, focusing on areas where the concentration of cancer diagnosis occurs to increase the total number of hospitals using Lymphoseek, and increasing the number of doses utilized per account, while continuing to evolve the brand.

Our operating expenses in recent years have been focused primarily on support of Lymphoseek, our Manocept platform, and NAV4694 and NAV5001 product development. We incurred approximately $6.5 million and $10.2 million in total on research and development activities during the nine-month periods ended September 30, 2016 and 2015, 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:

	Nine Months Ended September 30,	
Development Program *	**2016**	**2015**
Lymphoseek	$ 1,060,459	$ 1,581,037
Manocept Platform	663,536	683,298
Macrophage Therapeutics	561,601	418,633
NAV4694	1,332,369	3,092,864
NAV5001	101,997	194,153

* Certain development program expenditures were offset by grant reimbursement revenues totaling $2.0 million and $1.2 million during the nine-month periods ended September 30, 2016 and 2015, respectively.

We expect to continue the advancement of our efforts with Lymphoseek and our Manocept platform during the remainder of 2016 and into 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 and drug production 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 2016 than in 2015. This estimate excludes charges related to our subsidiary, Macrophage Therapeutics, Inc., which are currently expected to be funded separately.

Lymphoseek was approved and indicated for use in lymphatic mapping in patients with breast cancer and melanoma by the FDA in March 2013, with expanded use of Lymphoseek indicated for guiding sentinel lymph node biopsy in head and neck cancer patients with squamous cell carcinoma of the oral cavity approval in June 2014, and for lymphatic mapping in solid tumors and sentinel lymph node detection for breast cancer and melanoma as well as with or without scintigraphic imaging, known as lymphoscintigraphy, in October 2014. Lymphoseek was also 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 in November 2014.

Although our marketing partners have historically shared a portion of the direct marketing, sales and distribution costs related to the sale of Lymphoseek, we expect to incur ongoing costs to support product marketing efforts targeting surgical oncologists at the core of the oncology treatment team, as well as medical education-related and market outreach activities associated with Lymphoseek commercialization, if the Proposed Transaction with Cardinal Health (discussed below) does not close successfully. Additionally, we anticipate that we will incur costs related to supporting the other product, regulatory, manufacturing and commercial activities related to the potential marketing registration and sale of Lymphoseek in other markets, including a reduced-mass vial which recently received a positive regulatory opinion for marketing in the EU. We also expect to incur costs related to ongoing clinical development efforts to support the use of Lymphoseek in additional cancer types, although we expect those development programs to be supported by Cardinal Health following the closing of the Proposed Transaction. There can be no assurance that Lymphoseek will achieve regulatory approval in any other market outside the U.S. or EU, or if approved in those markets, that it will achieve market acceptance in the U.S., EU or any other market.

We are currently evaluating 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. In the near-term, our more active development efforts with respect to the Manocept platform will likely be limited to such evaluations. 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.

On September 5, 2016, the Company entered into a non-binding LOI with Cardinal Health pursuant to which Cardinal Health intends to acquire the Company's Lymphoseek Product and Acquired Assets and assume certain liabilities associated with the Proposed Transaction. The purchase price for the Proposed Transaction shall consist of (i) $80 million in cash payable at closing (reduced to the extent the amount of transferred Product inventory is less than $6 million), plus (ii) annual earn-out and milestone payments based upon the volume of Product sales. For the first three years, the earn-out payments shall be no less than $6.7 million per year. In no event will the entire purchase price, including all earn-out payments, exceed $310 million.

As part of the Proposed Transaction, the parties have agreed that simultaneous with the closing, subject to certain conditions, Cardinal Health will License Back to the Company, on a perpetual royalty free basis, certain rights to the Acquired Assets necessary for the Company to (i) develop, manufacture, market, sell and distribute new pharmaceutical and other products on an exclusive basis so long as such products do not compete with the Product, and (ii) manufacture, market, sell and distribute the Product throughout the world other than in North America on a non-exclusive basis.

Also as part of the Proposed Transaction, the Company shall grant to Cardinal Health five (5) year warrants to purchase up to 10 million shares of the Company's common stock, par value $.001 per share, at an exercise price of $1.50 per share and provide Cardinal Health with a right of first offer related to the assets covered by the License Back and new products developed by the Company in certain circumstances during the life of the Product's patents.

The parties intend to negotiate and execute definitive agreements for the Proposed Transaction with customary provisions for a transaction of this size and scope, including representations and warranties regarding the Company, its business, and the Acquired Assets, indemnification of Cardinal Health by the Company, covenants and closing conditions. The closing of the Proposed Transaction is subject to, among other things, the satisfactory completion of due diligence by Cardinal Health and approval of the Company's stockholders.

Unless written notice is given to the Company that Cardinal Health is ceasing further discussions related to the Proposed Transaction, the Company has agreed not to initiate or enter into any discussions with any third party regarding a possible sale of any equity or material assets of the Company or its subsidiaries for a period of thirty days from the date of the LOI. If the Company does not consummate a transaction with Cardinal Health as contemplated by the LOI and at any time within 180 days of the date of the LOI consummates one or more transactions that, directly or indirectly, result in a sale, license or other transfer of the Product, or all or substantially all of the Company's assets, then a certain Supply and Distribution Agreement between the Company and Cardinal Health shall automatically be extended for an additional three-year period. The parties have agreed that the provisions described in this paragraph shall be binding.

The Company intends to use the majority of the initial proceeds from the Proposed Transaction to pay off the loans to CRG and Platinum, and use the remainder to fund operations in the near term. If the Proposed Transaction closes, it will significantly improve our financial condition and our ability to continue as a going concern.

Results of Operations

Three Months Ended September 30, 2016 and 2015

Lymphoseek Sales and Margins. Net sales of Lymphoseek were $6.7 million during the third quarter of 2016, compared to $3.0 million during the same period of 2015. Net sales of Lymphoseek during the third quarter of 2016 included $500,000 related to reaching a sales milestone under the existing Cardinal distribution agreement, and reflected continued efforts to increase sales through increased adoption of Lymphoseek. Gross margins on net sales were 86% and 85% for the third quarters of 2016 and 2015, respectively. Cost of goods sold during the third quarters of 2016 and 2015 also included reserves for inventory obsolescence related to estimated product expiry of $43,000 and $48,000, respectively. Cost of goods sold in both periods included post-production testing activities required by regulatory authorities, which are charged as one-time period costs, and a royalty on net sales payable under our license agreement with UCSD.

Lymphoseek License Revenue. During the third quarters of 2016 and 2015, we recognized $667,000 and $250,000, respectively, of the $2.0 million non-refundable upfront payment received by the Company related to the Lymphoseek license and distribution agreement for Europe. The Company had been recognizing this revenue on a straight-line basis over two years, however the remaining deferred revenue of $417,000 was recognized upon obtaining European approval of a reduced-mass vial in September 2016, five months earlier than originally anticipated. During the third quarter of 2016, we also recognized $500,000 of milestone revenue upon obtaining European approval of the reduced-mass vial, as well as $127,000 reimbursement of certain clinical development costs, in accordance with the terms of the Lymphoseek distribution agreement for Europe. During the third quarter of 2015, we recognized $300,000 of Lymphoseek license revenue from a non-refundable milestone payment related to the Lymphoseek distribution agreement for China, for which the Company has no future obligations.

Grant and Other Revenue. During the third quarter of 2016, we recognized $511,000 of grant and other revenue as compared to $477,000 in the third quarter of 2015. Grant revenue during the third quarter of 2016 was primarily related to SBIR grants from the NIH supporting Manocept, Lymphoseek, therapeutic and NAV4694 development. Grant revenue during the third quarter of 2015 was primarily related to SBIR grants from the NIH supporting NAV4694, Manocept and Lymphoseek development. Grant and other revenue for the third quarter of 2015 also included revenue related to services provided to R-NAV for Manocept development.

Research and Development Expenses. Research and development expenses decreased $2.6 million, or 67%, to $1.3 million during the third quarter of 2016 from $3.9 million during the same period in 2015. The decrease was primarily due to net decreases in drug project expenses related to (i) decreased NAV4694 development costs of $1.4 million including decreased clinical trial costs, manufacturing-related activities and licensing costs, while we continued our efforts to divest the program; (ii) decreased Lymphoseek development costs of $636,000 including decreased manufacturing-related activities, pre-clinical testing, clinical trial costs, and regulatory costs; and (iii) decreased Manocept development costs of $160,000 including decreased pre-clinical testing, license fees, and manufacturing-related activities, offset by increased clinical trial costs. The net decrease in research and development expenses was also due to decreased compensation including incentive-based awards of $396,000 related to decreased headcount.

Selling, General and Administrative Expenses. Selling, general and administrative expenses decreased $1.0 million, or 25%, to $2.9 million during the third quarter of 2016 from $3.9 million during the same period in 2015. The net decrease was primarily due to decreased selling, general and administrative compensation including incentive-based awards of $364,000 related to decreased headcount coupled with decreased costs for legal and professional services, market development expenses related to Lymphoseek, and investor relations.

Other Income (Expense). Other expense, net, was $3.4 million during the third quarter of 2016 as compared to other expense, net of $3.7 million during the same period in 2015. Interest expense, net increased $418,000 to $2.6 million during the third quarter of 2016 from $2.1 million for the same period in 2015, primarily due to increased balances on the CRG Term Loan and Platinum Note, offset by the lower interest rate related to the Platinum Note in the third quarter of 2016 versus the same period in 2015. Of this interest expense, $65,000 in the third quarter of 2015 was non-cash in nature related to the amortization of debt issuance costs and debt discounts related to the CRG Term Loan. An additional $190,000 and $802,000 of this interest expense was compounded and added to the balance of our notes payable during the third quarters of 2016 and 2015, respectively. For the third quarters of 2016 and 2015, we recorded non-cash expense of $839,000 and $1.6 million, respectively, related to changes in the estimated fair value of financial instruments.

Nine Months Ended September 30, 2016 and 2015

Lymphoseek Sales and Margins. Net sales of Lymphoseek were $14.7 million during the first nine months of 2016, compared to $6.8 million during the same period of 2015. Net sales of Lymphoseek during the first nine months of 2016 included $500,000 related to reaching a sales milestone under the existing Cardinal distribution agreement, and reflected continued efforts to increase sales through increased adoption of Lymphoseek. Gross margins on net sales were 86% and 82% for the first nine months of 2016 and 2015, respectively. Cost of goods sold in the first nine months of 2015 included a net benefit of $247,000 related to our ability to sell certain previously reserved inventory, partially offset by net inventory losses of $93,000 related to a production matter. Cost of goods sold in the first nine months of 2016 and 2015 also included reserves for inventory obsolescence totaling $43,000 and $48,000, respectively, related to estimated product expiry. Cost of goods sold in both periods included post-production testing activities required by regulatory authorities, which are charged as one-time period costs, and a royalty on net sales payable under our license agreement with UCSD.

Lymphoseek License Revenue. During the first nine months of 2016 and 2015, we recognized $1.2 million and $583,000, respectively, of the $2.0 million non-refundable upfront payment received by the Company related to the Lymphoseek license and distribution agreement for Europe. The Company had been recognizing this revenue on a straight-line basis over two years, however the remaining deferred revenue of $417,000 was recognized upon obtaining European approval of a reduced-mass vial in September 2016, five months earlier than originally anticipated. During the first nine months of 2016, we also recognized $500,000 of milestone revenue upon obtaining European approval of the reduced-mass vial, as well as $127,000 reimbursement of certain clinical development costs, in accordance with the terms of the Lymphoseek distribution agreement for Europe. During the first nine months of 2015, we recognized $300,000 of Lymphoseek license revenue from a non-refundable milestone payment related to the Lymphoseek distribution agreement for China, for which the Company has no future obligations.

Grant and Other Revenue. During the first nine months of 2016, we recognized $2.1 million of grant and other revenue as compared to $1.3 million during the same period of 2015. Grant revenue during the first nine months of 2016 was primarily related to SBIR grants from the NIH supporting NAV4694, Manocept, Lymphoseek and therapeutic development. Grant revenue during the first nine months of 2015 was primarily related to SBIR grants from the NIH supporting NAV4694, Lymphoseek and Manocept development. Grant and other revenue for the first nine months of 2016 included $85,000 of revenue from our marketing partners in Europe and China related to specific development work performed at their request.

Research and Development Expenses. Research and development expenses decreased $3.7 million, or 37%, to $6.5 million during the first nine months of 2016 from $10.2 million during the same period in 2015. The decrease was primarily due to decreased compensation including incentive-based awards and other expenses related to net decreased headcount of $1.4 million following the first quarter 2015 reduction in force, coupled with net decreases in drug project expenses related to (i) decreased NAV4694 development costs of $1.8 million including decreased clinical trial costs and manufacturing-related activities offset by increased licensing costs, while we continued our efforts to divest the program; (ii) decreased Lymphoseek development costs of $521,000 including decreased manufacturing-related activities and pre-clinical testing, offset by increased regulatory and clinical trial costs; and (iii) decreased NAV5001 development costs of $92,000 including decreased manufacturing-related activities and clinical trial costs; offset by (iv) increased therapeutics development costs of $143,000 including increased consulting costs, offset by decreased scientific advisory board fess and pre-clinical testing.

Selling, General and Administrative Expenses. Selling, general and administrative expenses decreased $3.6 million, or 26%, to $9.9 million during the first nine months of 2016 from $13.5 million during the same period in 2015. The net decrease was primarily due to decreased general and administrative headcount of $2.1 million following the first quarter 2015 reduction in force coupled with decreased costs for business development consulting services, contracted medical science liaisons, market development expenses related to Lymphoseek, license fees, and investor relations, offset by increased commercial and medical headcount of $508,000 coupled with increased legal and professional services.

Other Income (Expense). Other expense, net, was $10.6 million during the first nine months of 2016 as compared to other expense, net of $9.1 million during the same period in 2015. Interest expense, net increased $7.6 million to $12.3 million during the first nine months of 2016 from $4.7 million for the same period in 2015, due in part to the higher outstanding balances and higher interest rates related to the CRG Term Loan in 2015 versus the Oxford Notes in 2015, coupled with the higher outstanding balances and higher average interest rates related to the Platinum Note in 2016 versus 2015. Of this interest expense, $2.1 million and $424,000 in the first nine months of 2016 and 2015, respectively, was non-cash in nature related to the amortization of debt issuance costs and debt discounts related to the CRG Term Loan and Oxford Notes. An additional $1.4 million and $1.2 million of this interest expense was compounded and added to the balance of our notes payable during the first six months of 2016 and 2015, respectively. CRG collection fees of $778,000, a prepayment premium of $2.1 million, and the remaining unamortized balance of the CRG debt discount of $2.0 million were also recorded as interest expense during the first nine months of 2016. For the first nine months of 2016 and 2015, we recorded non-cash income (expense) of $1.8 million and ($1.7 million), respectively, related to changes in the estimated fair value of financial instruments. During the first nine months of 2016 and 2015, we recorded non-cash equity in the loss of R-NAV of $15,000 and $295,000, respectively. During the first nine months of 2016, we also recorded a non-cash loss on the disposal of our investment in R-NAV of $40,000. During the first nine months of 2015, we recorded $2.4 million of losses on the extinguishment of the Oxford Notes.

Liquidity and Capital Resources

Cash balances decreased to $810,000 at September 30, 2016 from $7.2 million at December 31, 2015. The net decrease was primarily due to $4.1 million cash withdrawn by CRG for collection fees, prepayment premium and a backend facility fee, and $3.5 million restricted cash in a pledged collateral account over which CRG has control and a court escrow account, offset by $1.3 million provided by operations.

All of our material assets, except our intellectual property, have been pledged as collateral for our borrowings under the CRG Loan Agreement. In addition to the security interest in our assets, the CRG Loan Agreement carries covenants that impose significant requirements on us, including, among others, requirements that we (1) pay all principal, interest and other charges on the outstanding balance of the borrowed funds when due; (2) maintain liquidity of at least $5 million during the term of the CRG Loan Agreement; and (3) meet certain annual EBITDA or revenue targets ($22.5 million of Lymphoseek sales revenue in 2016) as defined in the CRG Loan Agreement. The events of default under the CRG Loan Agreement also include a failure of Platinum to perform its funding obligations under the Platinum Loan Agreement at any time as to which the Company had negative EBITDA for the most recent fiscal quarter, as a result either of Platinum's repudiation of its obligations under the Platinum Loan Agreement, or the occurrence of an insolvency event with respect to Platinum. An event of default would entitle 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.

During the second quarter 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.

On July 13, 2016, a hearing was held in the District Court of Harris County, Texas with respect to an application for temporary injunction (ATI) filed by CRG in June 2016. At the conclusion of the hearing, the Court ordered the parties to mediation and stayed any ruling on CRG's request for injunctive relief until after a mediation has been completed. On July 20, the parties participated in

mediation but were not successful in reaching an agreement. On July 29, 2016, the Harris County, Texas judge recused herself from the case, citing inability to be impartial. A new judge was appointed on July 29, 2016.

On August 30, 2016, the District Court of Harris County, Texas granted CRG's ATI. The Court provided the Company with 21 days to enter into the requisite account control agreements with CRG. In September 2016, the ATI was superseded by the requirement to maintain $2.5 million in a pledged collateral account that is subject to an account control agreement. The Order granting the ATI is currently on appeal to the Fourteenth Court of Appeals. Briefing is expected to be completed by early December 2016, after which a date will be set for oral arguments.

Discovery is ongoing in the Texas court action; the discovery period ends June 23, 2017. CRG filed an objection to the supersedeas that was heard on October 31, 2016, during which the court ruled that an additional $500,000 should be placed in the pledged collateral account within ten days of the ruling. In addition, CRG has filed a motion for partial summary judgment that currently is set for hearing on December 12, 2016. The Company is preparing responses to the motion for partial summary judgment. The trial date is currently set for July 3, 2017.

In June 2016, CRG contacted our primary distribution partner, Cardinal Health, and demanded that Cardinal Health make all future payments for Lymphoseek sales directly to CRG, rather than to Navidea. Cardinal Health filed an interpleader in the Franklin County, Ohio Court of Common Pleas, requesting that the court make a determination as to whom Cardinal Health should make such payments. Rulings on June 28, 2016 and August 1, 2016 resulted in $1.0 million of Cardinal Health payments being placed in escrow with the court, with the remaining Cardinal Health payments going directly to the Company.

In October 2016, a revised temporary restraining order was issued, allowing the Company to receive 100% of the receivables due from Cardinal Health, with an additional $1.0 million deposited in the pledged collateral account by the Company as a bond. Further, the court ruled that the Company remain current on its quarterly interest payments to CRG. On October 7, 2016 the Company paid $1.3 million to CRG to cover the third quarter 2016 interest payment. The $1.0 million previously deposited by Cardinal Health in the Court's registry as a bond will also be transferred to the pledged collateral account. CRG has filed a motion to dismiss the Company's cross-claims in Cardinal Health's interpleader action. The Company is in the process of responding to CRG's motion to dismiss.

The Company maintains that CRG's allegations of multiple events of default under the CRG Loan Agreement are without merit and the Company believes it has defenses against these claims. Furthermore, the Company believes that CRG's actions constitute a material breach of the CRG Loan Agreement and therefore, the Company is no longer subject to certain provisions of the CRG Loan Agreement. The Company believes that its best course of action is to pay off or refinance the CRG debt and pursue claims for damages. The Company is continuing to explore alternative financing arrangements, including the Proposed Transaction with Cardinal Health, in order to pay off or refinance the CRG debt. There can be no assurance that CRG will not prevail in exercising control over any additional banking arrangements that the Company creates, that the Company will be able to pay off or refinance the CRG debt or that the Company will be successful in its claims for damages. In light of current circumstances, the ability of the Company to continue as a going concern is in substantial doubt and dependent upon its ability to generate sufficient cash flow to sustain its operations on a timely basis, to obtain additional financing as may be required, and to pay off or refinance the CRG debt.

In addition, the Platinum Loan Agreement carries standard non-financial covenants typical for commercial loan agreements, many of which are similar to those contained in the CRG Loan Agreement, 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 terminate our ability to obtain additional draws under the Platinum Loan Agreement and accelerate the maturity of the debt, subject to the limitations of the Subordination Agreement with CRG. Such actions by Platinum could materially adversely affect our operations, results of operations and financial condition, including causing us to substantially 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.

As of September 30, 2016, the outstanding principal balance of the Platinum Note was approximately $9.3 million, with $27.3 million currently available under the credit facility. An additional $15 million is potentially available under the credit facility on terms to be negotiated. However, based on Platinum's recent filing for Chapter 15 bankruptcy protection, Navidea has substantial doubt about Platinum's ability to fund future draw requests under the credit facility. The inability to access credit under the Platinum Loan Agreement or other potentially available arrangements could materially adversely affect our operations and financial condition and our ability to continue as a going concern.

On September 5, 2016, the Company entered into a non-binding LOI with Cardinal Health pursuant to which Cardinal Health intends to acquire the Company's Lymphoseek Product and Acquired Assets and assume certain liabilities associated with the Proposed

Transaction. The purchase price for the Proposed Transaction shall consist of (i) $80 million in cash payable at closing (reduced to the extent the amount of transferred Product inventory is less than $6 million), plus (ii) annual earn-out and milestone payments based upon the volume of Product sales. For the first three years, the earn-out payments shall be no less than $6.7 million per year. In no event will the entire purchase price, including all earn-out payments, exceed $310 million.

As part of the Proposed Transaction, the parties have agreed that simultaneous with the closing, subject to certain conditions, Cardinal Health will License Back to the Company, on a perpetual royalty free basis, certain rights to the Acquired Assets necessary for the Company to (i) develop, manufacture, market, sell and distribute new pharmaceutical and other products on an exclusive basis so long as such products do not compete with the Product, and (ii) manufacture, market, sell and distribute the Product throughout the world other than in North America on a non-exclusive basis.

Also as part of the Proposed Transaction, the Company shall grant to Cardinal Health five (5) year warrants to purchase up to 10 million shares of the Company's common stock, par value $.001 per share, at an exercise price of $1.50 per share and provide Cardinal Health with a right of first offer related to the assets covered by the License Back and new products developed by the Company in certain circumstances during the life of the Product's patents.

The parties intend to negotiate and execute definitive agreements for the Proposed Transaction with customary provisions for a transaction of this size and scope, including representations and warranties regarding the Company, its business, and the Acquired Assets, indemnification of Cardinal Health by the Company, covenants and closing conditions. The closing of the Proposed Transaction is subject to, among other things, the satisfactory completion of due diligence by Cardinal Health and approval of the Company's stockholders.

Unless written notice is given to the Company that Cardinal Health is ceasing further discussions related to the Proposed Transaction, the Company has agreed not to initiate or enter into any discussions with any third party regarding a possible sale of any equity or material assets of the Company or its subsidiaries for a period of thirty days from the date of the LOI. If the Company does not consummate a transaction with Cardinal Health as contemplated by the LOI and at any time within 180 days of the date of the LOI consummates one or more transactions that, directly or indirectly, result in a sale, license or other transfer of the Product, or all or substantially all of the Company's assets, then a certain Supply and Distribution Agreement between the Company and Cardinal Health shall automatically be extended for an additional three-year period. The parties have agreed that the provisions described in this paragraph shall be binding.

The Company intends to use the majority of the initial proceeds from the Proposed Transaction to pay off the loans to CRG and Platinum, and use the remainder to fund operations in the near term. If the Proposed Transaction closes, it will significantly improve our financial condition and our ability to continue as a going concern.

Operating Activities. Cash from operations increased $16.2 million to $1.3 million provided during the first nine months of 2016 compared to $14.9 million used during the same period in 2015.

Accounts and other receivables decreased to $3.5 million at September 30, 2016 from $3.7 million at December 31, 2015, primarily due to the receipt of $1.2 million of royalties from Devicor associated with the 2011 sale of the GDS Business offset by increased receivables due from Cardinal Health resulting from the increase in sales of Lymphoseek and increased amounts due from our European distribution partner related to a milestone and clinical trial cost reimbursement.

Inventory levels increased to $805,000 at September 30, 2016 from $653,000 at December 31, 2015, primarily due to finished goods and materials inventory produced offset by materials used in production and finished goods inventory sold. We expect inventory levels to decrease during the remainder of 2016 as we manage our Lymphoseek inventory demands against our cash constraints.

Prepaid expenses and other current assets decreased to $840,000 at September 30, 2016 from $1.1 million at December 31, 2015, primarily due to amortization of prepaid insurance and FDA annual fees, offset by increased legal retainers related to the CRG litigation and FDA annual fees.

Accounts payable increased to $4.9 million at September 30, 2016 from $1.8 million at December 31, 2015, primarily due to net increased payables due to NAV4694, investor relations, legal and professional services and Lymphoseek vendors. Of the increased accounts payable, at least $840,000 is being disputed by the Company's current management. Accrued liabilities and other current liabilities increased to $7.2 million at September 30, 2016 from $3.0 million at December 31, 2015, primarily due to increased accruals for interest on the CRG debt, Lymphoseek royalties due to UCSD, and Macrophage Therapeutics costs, offset by decreased accruals for NAV4694 development costs and legal and professional services. 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 likely increases in legal and professional services related to the CRG litigation and planned increases in Manocept development.

Investing Activities. Investing activities used $39,000 during the first nine months of 2016 compared to $19,000 used during the same period in 2015. Net payments related to the disposal of our investment in R-NAV of $82,000 and capital expenditures of $2,000, primarily for computer equipment, were offset by proceeds from sales of capital equipment of $45,000 during the first nine months of 2016. Purchases of capital equipment of $30,000, primarily for Lymphoseek production equipment, and patent and trademark costs of

$27,000 were offset by proceeds from sales of equipment of $38,000 during the first nine months of 2015. We expect our overall capital expenditures for the remainder of 2016 will be lower than for the same period in 2015.

Financing Activities. Financing activities used $7.6 million during the first nine months of 2016 compared to providing $20.8 million during the same period in 2015. The $7.6 million used by financing activities in the first nine months of 2016 consisted primarily of payment of debt-related costs of $3.9 million, restrictions placed on cash in an account controlled by CRG of $3.5 million, and principal payments on notes payable of $189,000, all related to the CRG debt. The $20.8 million provided by financing activities in the first nine months of 2015 consisted primarily of proceeds from the CRG Term Loan of $50.0 million, draws under the Platinum credit facility of $4.5 million, and proceeds from issuance of MT Preferred Stock of $500,000, offset by principal payments on the Oxford Notes of $30.0 million and payment of debt-related costs of $3.9 million.

Investment in Macrophage Therapeutics, Inc.

In December 2015 and May 2016, Platinum contributed a total of $200,000 to Macrophage Therapeutics, Inc. MT was not obligated to provide anything in return, although it was considered likely that the MT Board would ultimately authorize some form of compensation to Platinum. As such, the Company recorded the $200,000 as a current liability pending determination of the form of compensation.

In July 2016, MT's Board of Directors authorized modification of the original investments of $300,000 by Platinum and $200,000 by Dr. Goldberg to a convertible preferred stock with a 10% PIK coupon retroactive to the time the initial investments were made. The conversion price of the preferred will remain at the $500 million initial market cap but a full ratchet will be 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 authorized issuance of additional convertible preferred stock with the same terms to Platinum as compensation for the additional $200,000 of investments made in December 2015 and May 2016. 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.

Investment in R-NAV, LLC

Effective May 31, 2016, Navidea terminated its joint venture with R-NAV. Under the terms of the agreement, Navidea (1) transferred all of its shares of R-NAV, consisting of 1,500,000 Series A Preferred Units and 3,500,000 Common Units, to R-NAV; and (2) paid $110,000 in cash to R-NAV. In exchange, R-NAV (1) transferred all of its shares of TcRA to Navidea, thereby returning the technology licensed to TcRA to Navidea; and (2) forgave the $333,333 remaining on the promissory note. The Company's obligation to provide $500,000 of in-kind services to R-NAV was being recognized as those services were provided. The Company provided $15,000 of in-kind services during the five-month period ended May 31, 2016. As of the date of termination, the Company had $383,000 of in-kind services remaining to provide under this obligation. This obligation ceased on May 31, 2016 under the terms of the agreement. Neither Navidea nor R-NAV has any further obligations of any kind to either party.

Capital Royalty Partners II, L.P. Debt

In May 2015, Navidea and its subsidiary Macrophage Therapeutics, Inc., as guarantor, executed a Term Loan Agreement with CRG in its capacity as a lender and as control agent for other affiliated lenders party to the CRG Loan Agreement in which the Lenders agreed to make a term loan to the Company in the aggregate principal amount of $50 million, 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 nine-month period ended September 30, 2016, $553,000 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, the Company stopped compounding interest in the second quarter of 2016 and began recording accrued interest. As of September 30, 2016, $4.7 million of accrued interest is included in accrued liabilities and other on the consolidated balance sheets. As of September 30, 2016, the outstanding principal balance of the CRG Term Loan was $51.7 million.

The CRG Term Loan is collateralized by a security interest in substantially all of the Company's assets. In addition, the CRG Loan Agreement requires that the Company adhere to certain affirmative and negative covenants, including financial reporting requirements and a prohibition against the incurrence of indebtedness, or creation of additional liens, other than as specifically permitted by the terms of the CRG Loan Agreement. The Lenders may accelerate the payment terms of the CRG Loan Agreement upon the occurrence of certain events of default set forth therein, which include the failure of the Company to make timely payments of amounts due under the CRG Loan Agreement, the failure of the Company to adhere to the covenants set forth in the CRG Loan Agreement, and the insolvency of the Company. The covenants of the CRG Loan Agreement include a covenant that the Company shall have EBITDA of no less than $5 million in each calendar year during the term or revenues from sales of Lymphoseek in each calendar year during the term of at least $22.5 million in 2016, with the target minimum revenue increasing in each year thereafter until reaching $45 million in 2020. However, if the Company were to fail to meet the applicable minimum EBITDA or revenue target in any calendar year, the CRG Loan Agreement provides the Company a cure right if it raises 2.5 times the EBITDA or revenue shortfall in equity or subordinated debt and deposits such funds in a separate blocked account. Additionally, the Company must maintain liquidity, defined as the balance of unencumbered cash and permitted cash equivalent investments, of at least $5 million during the term of the CRG Term Loan. The events of default under the CRG Loan Agreement also include a failure of Platinum to perform its funding

obligations under the Platinum Loan Agreement at any time as to which the Company had negative EBITDA for the most recent fiscal quarter, as a result either of Platinum's repudiation of its obligations under the Platinum Loan Agreement, or the occurrence of an insolvency event with respect to Platinum. An event of default would entitle 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.

During the second quarter 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.

On July 13, 2016, a hearing was held in the District Court of Harris County, Texas with respect to an application for temporary injunction (ATI) filed by CRG in June 2016. At the conclusion of the hearing, the Court ordered the parties to mediation and stayed any ruling on CRG's request for injunctive relief until after a mediation has been completed. On July 20, the parties participated in mediation but were not successful in reaching an agreement. On July 29, 2016, the Harris County, Texas judge recused herself from the case, citing inability to be impartial. A new judge was appointed on July 29, 2016.

On August 30, 2016, the District Court of Harris County, Texas granted CRG's ATI. The Court provided the Company with 21 days to enter into the requisite account control agreements with CRG. In September 2016, the ATI was superseded by the requirement to maintain $2.5 million in a pledged collateral account that is subject to an account control agreement. The Order granting the ATI is currently on appeal to the Fourteenth Court of Appeals. Briefing is expected to be completed by early December 2016, after which a date will be set for oral arguments.

Discovery is ongoing in the Texas court action; the discovery period ends June 23, 2017. CRG filed an objection to the supersedeas that was heard on October 31, 2016, during which the court ruled that an additional $500,000 should be placed in the pledged collateral account within ten days of the ruling. In addition, CRG has filed a motion for partial summary judgment that currently is set for hearing on December 12, 2016. The Company is preparing responses to the motion for partial summary judgment. The trial date is currently set for July 3, 2017.

In June 2016, CRG contacted our primary distribution partner, Cardinal Health, and demanded that Cardinal Health make all future payments for Lymphoseek sales directly to CRG, rather than to Navidea. Cardinal Health filed an interpleader in the Franklin County, Ohio Court of Common Pleas, requesting that the court make a determination as to whom Cardinal Health should make such payments. Rulings on June 28, 2016 and August 1, 2016 resulted in $1.0 million of Cardinal Health payments being placed in escrow with the court, with the remaining Cardinal Health payments going directly to the Company.

In October 2016, a revised temporary restraining order was issued, allowing the Company to receive 100% of the receivables due from Cardinal Health, with an additional $1.0 million deposited in the pledged collateral account by the Company as a bond. Further, the court ruled that the Company remain current on its quarterly interest payments to CRG. On October 7, 2016 the Company paid $1.3 million to CRG to cover the third quarter 2016 interest payment. The $1.0 million previously deposited by Cardinal Health in the Court's registry as a bond will also be transferred to the pledged collateral account. CRG has filed a motion to dismiss the Company's cross-claims in Cardinal Health's interpleader action. The Company is in the process of responding to CRG's motion to dismiss.

The Company maintains that CRG's allegations of multiple events of default under the CRG Loan Agreement are without merit and the Company believes it has defenses against these claims. Furthermore, the Company believes that CRG's actions constitute a material breach of the CRG Loan Agreement and therefore, the Company is no longer subject to certain provisions of the CRG Loan Agreement. The Company believes that its best course of action is to pay off or refinance the CRG debt and pursue claims for damages. The Company is continuing to explore alternative financing arrangements, including the Proposed Transaction with Cardinal Health, in order to pay off or refinance the CRG debt. There can be no assurance that CRG will not prevail in exercising control over any additional banking arrangements that the Company creates, that the Company will be able to pay off or refinance the CRG debt or that the Company will be successful in its claims for damages. In light of current circumstances, the ability of the Company to continue as a going concern is in substantial doubt and dependent upon its ability to generate sufficient cash flow to sustain its operations on a timely basis, to obtain additional financing as may be required, and to pay off or refinance the CRG debt. Based on CRG's claims that the Company is in default under the terms of the CRG Loan Agreement, and in accordance with current accounting guidance, the Company has classified the balance of the CRG Term Loan as a current liability as of September 30, 2016.

Oxford Debt

In March 2014, we executed a Loan and Security Agreement (the Oxford Loan Agreement) with Oxford Finance, LLC (Oxford), providing for a loan to the Company of $30 million. Pursuant to the Oxford Loan Agreement, we issued Oxford: (1) Term Notes in the aggregate principal amount of $30 million, bearing interest at 8.5% (the Oxford Notes), and (2) Series KK warrants to purchase an aggregate of 391,032 shares of our common stock at an exercise price of $1.918 per share, expiring in March 2021 (the Series KK warrants). We began making monthly payments of interest only on April 1, 2014, and monthly payments of principal and interest beginning April 1, 2015. In May 2015, in connection with the consummation of the CRG Loan Agreement, the Company repaid all amounts outstanding under the Oxford Loan Agreement. The payoff amount of $31.6 million included payments of $289,000 as a pre-payment fee and $2.4 million as an end-of-term final payment fee.

Platinum Credit Facility

The Platinum Loan Agreement, as amended, provides us with a credit facility of up to $50 million. During the first nine months of 2016, $814,000 of interest was compounded and added to the balance of the Platinum Note. As of September 30, 2016, the outstanding principal balance of the Platinum Note was approximately $9.3 million, with $27.3 million currently available under the credit facility. An additional $15 million is potentially available under the credit facility on terms to be negotiated. However, based on Platinum's recent filing for Chapter 15 bankruptcy protection, Navidea has substantial doubt about Platinum's ability to fund future draw requests under the credit facility. The inability to access credit under the Platinum Loan Agreement or other potentially available arrangements could materially adversely affect our operations and financial condition and our ability to continue as a going concern.

In addition, the Platinum Loan Agreement carries standard non-financial covenants typical for commercial loan agreements, many of which are similar to those contained in the CRG Loan Agreement, 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 terminate our ability to obtain additional draws under the Platinum Loan Agreement and accelerate the maturity of the debt, subject to the limitations of the Subordination Agreement with CRG. Such actions by Platinum could materially adversely affect our operations, results of operations and financial condition, including causing us to substantially 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.

Cardinal Health Letter of Intent

On September 5, 2016, the Company entered into a non-binding LOI with Cardinal Health pursuant to which Cardinal Health intends to acquire the Company's Lymphoseek Product and Acquired Assets and assume certain liabilities associated with the Proposed Transaction. The purchase price for the Proposed Transaction shall consist of (i) $80 million in cash payable at closing (reduced to the extent the amount of transferred Product inventory is less than $6 million), plus (ii) annual earn-out and milestone payments based upon the volume of Product sales. For the first three years, the earn-out payments shall be no less than $6.7 million per year. In no event will the entire purchase price, including all earn-out payments, exceed $310 million.

As part of the Proposed Transaction, the parties have agreed that simultaneous with the closing, subject to certain conditions, Cardinal Health will License Back to the Company, on a perpetual royalty free basis, certain rights to the Acquired Assets necessary for the Company to (i) develop, manufacture, market, sell and distribute new pharmaceutical and other products on an exclusive basis so long as such products do not compete with the Product, and (ii) manufacture, market, sell and distribute the Product throughout the world other than in North America on a non-exclusive basis.

Also as part of the Proposed Transaction, the Company shall grant to Cardinal Health five (5) year warrants to purchase up to 10 million shares of the Company's common stock, par value $.001 per share, at an exercise price of $1.50 per share and provide Cardinal Health with a right of first offer related to the assets covered by the License Back and new products developed by the Company in certain circumstances during the life of the Product's patents.

The parties intend to negotiate and execute definitive agreements for the Proposed Transaction with customary provisions for a transaction of this size and scope, including representations and warranties regarding the Company, its business, and the Acquired Assets, indemnification of Cardinal Health by the Company, covenants and closing conditions. The closing of the Proposed Transaction is subject to, among other things, the satisfactory completion of due diligence by Cardinal Health and approval of the Company's stockholders.

Unless written notice is given to the Company that Cardinal Health is ceasing further discussions related to the Proposed Transaction, the Company has agreed not to initiate or enter into any discussions with any third party regarding a possible sale of any equity or material assets of the Company or its subsidiaries for a period of thirty days from the date of the LOI. If the Company does not consummate a transaction with Cardinal Health as contemplated by the LOI and at any time within 180 days of the date of the LOI consummates one or more transactions that, directly or indirectly, result in a sale, license or other transfer of the Product, or all or substantially all of the Company's assets, then a certain Supply and Distribution Agreement between the Company and Cardinal Health shall automatically be extended for an additional three-year period. The parties have agreed that the provisions described in this paragraph shall be binding.

The Company intends to use the majority of the initial proceeds from the Proposed Transaction to pay off the loans to CRG and Platinum, and use the remainder to fund operations in the near term. If the Proposed Transaction closes, it will significantly improve our financial condition and our ability to continue as a going concern.

Summary

Our future liquidity and capital requirements will depend on a number of factors, including the closing of the Proposed Transaction with Cardinal Health, the outcome of the CRG litigation, our ability to achieve market acceptance of our products, our ability to comply with the covenants of our debt agreements, 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.

The Company is continuing to explore alternative financing arrangements, including the Proposed Transaction with Cardinal Health, in order to pay off or refinance the CRG debt. The Company believes that its best course of action is to pay off or refinance the CRG debt and pursue claims for damages. 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 levels that can be increasingly offset by growing Lymphoseek revenue. Substantial progress on the Manocept platform has resulted in several promising opportunities, including the formation of Macrophage Therapeutics, Inc. in January 2015. Additionally, the Company's Proposed Transaction with Cardinal Health, if closed successfully, will significantly improve our financial condition and our ability to continue as a going concern.

We plan to focus our resources for the remainder of 2016 primarily on closing the Proposed Transaction with Cardinal Health, increasing sales of Lymphoseek, development of products based on the Manocept platform, and defending our position related to CRG's claims of default. 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 satisfactory completion of due diligence by Cardinal Health and approval of the Proposed Transaction by the Company's stockholders, the outcome of the 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 2015 and the first nine months of 2016, 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. All of the above factors raise substantial doubt about our ability to continue as a going concern.

Recent Accounting Standards

In August 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2014-15, *Presentation of Financial Statements-Going Concern*. ASU 2014-15 defines when and how companies are required to disclose going concern uncertainties, which must be evaluated each interim and annual period. ASU 2014-15 requires management to determine whether substantial doubt exists regarding the entity's going concern presumption. Substantial doubt about an entity's ability to continue as a going concern exists when relevant conditions and events, considered in the aggregate, indicate that it is probable that the entity will be unable to meet its obligations as they become due within one year after the date that the financial statements are issued (or available to be issued). If substantial doubt exists, certain disclosures are required; the extent of those disclosures depends on an evaluation of

management's plans (if any) to mitigate the going concern uncertainty. ASU 2014-15 is effective prospectively for annual periods ending after December 15, 2016, and to annual and interim periods thereafter. Early adoption is permitted. We do not expect the adoption of ASU 2014-15 to have a material effect on our consolidated financial statements, however it may affect our disclosures.

In March 2016, the FASB issued ASU No. 2016-08, *Revenue from Contracts with Customers – Principal versus Agent Considerations (Reporting Revenue Gross versus Net)*. ASU 2016-08 does not change the core principle of the guidance, rather it clarifies the implementation guidance on principal versus agent considerations. ASU 2016-08 clarifies the guidance in ASU No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*, which is not yet effective. The effective date and transition requirements for ASU 2016-08 are the same as for ASU 2014-09, which was deferred by one year by ASU No. 2015-14, *Revenue from Contracts with Customers – Deferral of the Effective Date.* Public business entities should adopt the new revenue recognition standard for annual reporting periods beginning after December 15, 2017, including interim periods within that year. Early adoption is permitted only as of annual reporting periods beginning after December 15, 2016, including interim periods within that year. We are currently evaluating the potential impact that the adoption of ASU 2014-09 may have on our consolidated financial statements.

In March 2016, the FASB issued ASU No. 2016-09, *Compensation – Stock Compensation.* 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. Some of the simplified areas apply only to nonpublic entities. ASU 2016-09 is effective for public business entities for annual periods beginning after December 15, 2016, and interim periods within those annual periods. Early adoption is permitted in any interim or annual period. If an entity early adopts ASU 2016-09 in an interim period, any adjustments should be reflected as of the beginning of the fiscal year that includes that interim period. Methods of adoption vary according to each of the amendment provisions. We are currently evaluating the potential impact that the adoption of ASU 2016-09 may have on our consolidated financial statements.

In April 2016, the FASB issued ASU No. 2016-10, *Revenue from Contracts with Customers – Identifying Performance Obligations and Licensing*. ASU 2016-10 does not change the core principle of the guidance, rather it clarifies the identification of performance obligations and the licensing implementation guidance, while retaining the related principles for those areas. ASU 2016-10 clarifies the guidance in ASU No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*, which is not yet effective. The effective date and transition requirements for ASU 2016-10 are the same as for ASU 2014-09, which was deferred by one year by ASU No. 2015-14, *Revenue from Contracts with Customers – Deferral of the Effective Date*. Public business entities should adopt the new revenue recognition standard for annual reporting periods beginning after December 15, 2017, including interim periods within that year. Early adoption is permitted only as of annual reporting periods beginning after December 15, 2016, including interim periods within that year. We are currently evaluating the potential impact that the adoption of ASU 2014-09 may have on our consolidated financial statements.

In May 2016, the FASB issued ASU No. 2016-12, *Revenue from Contracts with Customers – Narrow-Scope Improvements and Practical Expedients*. ASU 2016-12 does not change the core principle of the guidance, rather it affects only certain narrow aspects of Topic 606, including assessing collectability, presentation of sales taxes, noncash consideration, and completed contracts and contract modifications at transition. ASU 2016-12 affects the guidance in ASU No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*, which is not yet effective. The effective date and transition requirements for ASU 2016-12 are the same as for ASU 2014-09, which was deferred by one year by ASU No. 2015-14, *Revenue from Contracts with Customers – Deferral of the Effective Date*. Public business entities should adopt the new revenue recognition standard for annual reporting periods beginning after December 15, 2017, including interim periods within that year. Early adoption is permitted only as of annual reporting periods beginning after December 15, 2016, including interim periods within that year. We are currently evaluating the potential impact that the adoption of ASU 2014-09 may have on our consolidated financial statements.

In August 2016, the FASB issued ASU No. 2016-15, *Statement of Cash Flows – Classification of Certain Cash Receipts and Cash Payments*. ASU 2016-15 addresses certain specific cash flow issues with the objective of reducing the existing diversity in practice in how certain cash receipts and cash payments are presented and classified in the statement cash flows. ASU 2016-15 is effective for public business entities for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. Early adoption is permitted in any interim or annual period. If an entity early adopts ASU 2016-15 in an interim period, any adjustments should be reflected as of the beginning of the fiscal year that includes that interim period. ASU 2016-15 should be applied using a retrospective transition method to each period presented, with certain exceptions. We adopted ASU 2016-15 upon issuance, which resulted in debt prepayment costs being classified as financing costs rather than operating costs on the statement of cash flows.

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 sales of Lymphoseek. Our standard shipping terms are FOB shipping point, and title and risk of loss passes to the customer upon delivery to a carrier for shipment. We generally recognize sales revenue related to sales of our products when the products are shipped. Our customers have no right to return products purchased in the ordinary course of business, however, we may allow returns in certain circumstances based on specific agreements.

We earn additional revenues based on a percentage of the actual net revenues achieved by Cardinal Health on sales to end customers made during each fiscal year. The amount we charge Cardinal Health related to end customer sales of Lymphoseek are subject to a retroactive annual adjustment. To the extent that we can reasonably estimate the end customer prices received by Cardinal Health, we record sales based upon these estimates at the time of sale. If we are unable to reasonably estimate end customer sales prices related to products sold, we record revenue related to these product sales at the minimum (i.e., floor) price provided for under our distribution agreement with Cardinal Health.

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 generate additional revenue from grants to support various product development initiatives. We generally recognize grant revenue when expenses reimbursable under the grants have been paid and payments under the grants become contractually due. Lastly, we recognize revenues from the provision of services to R-NAV and its subsidiaries.

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. The fair value of each option award is estimated on the date of grant using the Black-Scholes option pricing model to value share-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.

- *Inventory Valuation.* We record our inventory at the lower of cost (first-in, first-out method) or market. Our valuation reflects our estimates of excess and obsolete inventory as well as inventory with a carrying value in excess of its net realizable value. Write-offs are recorded when product is removed from saleable inventory. We review inventory on hand at least quarterly and record provisions for excess and obsolete inventory based on several factors, including current assessment of future product demand, anticipated release of new products into the market and product expiration. Our industry is characterized by rapid product development and frequent new product introductions. Regulations regarding use and shelf life, product recalls and variation in product utilization all impact the estimates related to excess and obsolete inventory.
- *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.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk. As of September 30, 2016, our $810,000 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 September 30, 2016, 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%, (b) 10.0% and (c) the highest rate of interest payable pursuant to the CRG Term Loan plus 0.125%; all of the above rates reduced by 600 basis points (effective interest rate as of September 30, 2016 was 8.125%). Based on the effective rate of our variable-rate borrowings, which totaled approximately $9.3 million at September 30, 2016, an immediate one percentage point increase or 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 nine-month periods ended September 30, 2016 and 2015, we recorded foreign currency transaction gains (losses) of approximately $43,000 and $(32,000), respectively. Foreign currency transaction gains (losses) are included in other income (expense) in the consolidated Statements of Operations.

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 September 30, 2016, 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 Interim Chief Operating 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 September 30, 2016. 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 Interim Chief Operating Officer 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 our Interim Chief Operating 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.

Changes in Control Over Financial Reporting

During the quarter ended September 30, 2016, there were no changes in our internal control over financial reporting that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings

Section 16(b) Action

On August 12, 2015, a Navidea shareholder filed an action in the United States District Court for the Southern District of New York against two funds managed by Platinum Management (NY) LLC (Platinum) alleging violations of Section 16(b) of the Securities Exchange Act of 1934, as amended, in connection with purchases and sales of the Company's common stock by the Platinum funds, and seeking disgorgement of the short-swing profits realized by the funds (the Litigation). The Company was named as a nominal defendant in the Litigation.

The Litigation was resolved on the terms set forth in a settlement agreement (the Settlement Agreement). The Settlement Agreement was subject to a pending joint motion for approval. The Court approved the settlement on Friday, July 1, 2016. In accordance with the terms of the Settlement Agreement, the interest rate on the Platinum credit facility was reduced by 6% to 8.125% effective July 1, 2016. In addition, Platinum assumed the obligation to pay the legal costs associated with the Litigation.

Sinotau Litigation

On August 31, 2015, Sinotau Pharmaceutical Group (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 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.

In July 2016, the Company executed a term sheet with Cerveau Technologies, Inc. (Cerveau) as a designated party for the rights resulting from the relationship between Navidea and Sinotau. The term sheet outlined the terms of a potential agreement between the parties to sublicense NAV4694 to Cerveau in return for license fees, milestone payments and royalties. With the exception of certain provisions, the term sheet was non-binding and was subject to the agreement of AstraZeneca, from whom the Company has licensed the NAV4694 technology. The Company had 60 days to execute a definitive agreement, however no definitive agreement was reached. Discussions related to the potential partnering or divestiture of NAV4694 are ongoing.

CRG Litigation

During the second quarter 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.

On July 13, 2016, a hearing was held in the District Court of Harris County, Texas with respect to an application for temporary injunction (ATI) filed by CRG in June 2016. At the conclusion of the hearing, the Court ordered the parties to mediation and stayed any ruling on CRG's request for injunctive relief until after a mediation has been completed. On July 20, the parties participated in mediation but were not successful in reaching an agreement. On July 29, 2016, the Harris County, Texas judge recused herself from the case, citing inability to be impartial. A new judge was appointed on July 29, 2016.

On August 30, 2016, the District Court of Harris County, Texas granted CRG's ATI. The Court provided the Company with 21 days to enter into the requisite account control agreements with CRG. In September 2016, the ATI was superseded by the requirement to maintain $2.5 million in a pledged collateral account that is subject to an account control agreement. The Order granting the ATI is currently on appeal to the Fourteenth Court of Appeals. Briefing is expected to be completed by early December 2016, after which a date will be set for oral arguments.

Discovery is ongoing in the Texas court action; the discovery period ends June 23, 2017. CRG filed an objection to the supersedeas that was heard on October 31, 2016, during which the court ruled that an additional $500,000 should be placed in the pledged collateral account within ten days of the ruling. In addition, CRG has filed a motion for partial summary judgment that currently is set for hearing on December 12, 2016. The Company is preparing responses to the motion for partial summary judgment. The trial date is currently set for July 3, 2017.

In June 2016, CRG contacted our primary distribution partner, Cardinal Health, and demanded that Cardinal Health make all future payments for Lymphoseek sales directly to CRG, rather than to Navidea. Cardinal Health filed an interpleader in the Franklin County, Ohio Court of Common Pleas, requesting that the court make a determination as to whom Cardinal Health should make such payments. Rulings on June 28, 2016 and August 1, 2016 resulted in $1.0 million of Cardinal Health payments being placed in escrow with the court, with the remaining Cardinal Health payments going directly to the Company.

In October 2016, a revised temporary restraining order was issued, allowing the Company to receive 100% of the receivables due from Cardinal Health, with an additional $1.0 million deposited in the pledged collateral account by the Company as a bond. Further, the court ruled that the Company remain current on its quarterly interest payments to CRG. On October 7, 2016 the Company paid $1.3 million to CRG to cover the third quarter 2016 interest payment. The $1.0 million previously deposited by Cardinal Health in the Court's registry as a bond will also be transferred to the pledged collateral account. CRG has filed a motion to dismiss the Company's cross-claims in Cardinal Health's interpleader action. The Company is in the process of responding to CRG's motion to dismiss.

The Company maintains that CRG's allegations of multiple events of default under the CRG Loan Agreement are without merit and the Company believes it has defenses against these claims. Furthermore, the Company believes that CRG's actions constitute a material breach of the CRG Loan Agreement and therefore, the Company is no longer subject to certain provisions of the CRG Loan Agreement. The Company believes that its best course of action is to pay off or refinance the CRG debt and pursue claims for damages. The Company is continuing to explore alternative financing arrangements, including the Proposed Transaction with Cardinal Health, in order to pay off or refinance the CRG debt. There can be no assurance that CRG will not prevail in exercising control over any additional banking arrangements that the Company creates, that the Company will be able to pay off or refinance the CRG debt or that the Company will be successful in its claims for damages.

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. The Company intends to vigorously defend its position. In addition, the Company has filed counterclaims against Mr. Gonzalez. A three-person arbitration board has been chosen and a hearing is set for April 3-7, 2017 in Columbus, Ohio.

Former Director Litigation

On August 12, 2016, the Company commenced an action in the Superior Court of California for damages and injunctive relief against former Navidea Chairman and Macrophage Board Member Anton Gueth. The Complaint alleges, in part, that Mr. Gueth intentionally failed to disclose his prior existing relationship with CRG, in addition to multiple breaches including duty, loyalty and contract, interference and misappropriation. Litigation is currently stayed while the parties attempt to negotiate a settlement.

FTI Consulting, Inc. Litigation

On October 11, 2016, the Company was served with a Complaint filed in the Supreme Court of the State of New York, County of New York, alleging damages of at least $782,601.51 arising from investigative and consulting services that Plaintiff alleges it was retained by the Company to perform. The Company disputes the amount claimed to be due, as well as whether the services performed were properly authorized, and intends to vigorously defend the action.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

During the three-month period ended September 30, 2016, we issued 43,580 shares of our common stock to a member of our Board of Directors who elected to receive stock in lieu of cash compensation. The issuance of these securities was exempt from registration under Section 4(a)(2) of the Securities Act and Regulation D promulgated thereunder.

Item 6. Exhibits

10.1	Employment Agreement, dated September 22, 2016, between Navidea Biopharmaceuticals, Inc. and Michael M. Goldberg, M.D. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K/A filed September 27, 2016).
31.1	Certification of President and Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*
31.2	Certification of Interim Chief Operating Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*
32.1	Certification of President and 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 Interim Chief Operating 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 1a, 3, 4 and 5 are not applicable and have been omitted.

SIGNATURES

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

NAVIDEA BIOPHARMACEUTICALS, INC.
(the Company)
November 9, 2016

By:/s/ Michael M. Goldberg

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

By:/s/ Jed A. Latkin

Jed A. Latkin
Interim Chief Operating Officer
(duly authorized officer; principal financial and accounting officer)

INDEX TO EXHIBITS

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101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document*

* Filed herewith.
** Furnished herewith.

Exhibit 31.1

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

I, Michael M. Goldberg, 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.

November 9, 2016

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

Exhibit 31.2

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.

November 9, 2016

/s/ Jed A. Latkin
Jed A. Latkin
Interim Chief Operating Officer
(principal financial and accounting officer)

Exhibit 32.1

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

The undersigned hereby certifies that he is the duly appointed and acting President and 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.

November 9, 2016

/s/ Michael M. Goldberg

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

Exhibit 32.2

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.

November 9, 2016

/s/ Jed A. Latkin
Jed A. Latkin
Interim Chief Operating Officer
(principal financial and accounting officer)