NAVIDEA BIOPHARMACEUTICALS, INC.
Form 10-Q
May 16, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended March 31, 2016

o 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 x No o

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 x No o

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 x
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 o No x

Indicate the number of shares outstanding of each of the issuer’s classes of common stock, as of the latest practicable date: 155,612,734 shares of common stock, par value $.001 per share (as of the close of business on May 9, 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

	March 31, 2016 (unaudited)	December 31, 2015
ASSETS		
Current assets:		
Cash	$5,484,083	$7,166,260
Accounts and other receivables	2,800,039	3,703,186
Inventory, net	898,936	652,906
Prepaid expenses and other	853,066	1,054,822
Total current assets	10,036,124	12,577,174
Property and equipment	3,860,851	3,871,035
Less accumulated depreciation and amortization	2,079,269	1,943,427
	1,781,582	1,927,608
Patents and trademarks	222,590	233,596
Less accumulated amortization	38,149	47,438
	184,441	186,158
Other assets	281,534	273,573
Total assets	$12,283,681	$14,964,513
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$2,901,363	$1,767,523
Accrued liabilities and other	3,066,745	3,038,713
Deferred revenue, current	945,190	1,044,281
Notes payable, current, net of discounts of $1,960,631 and $0, respectively	50,179,537	333,333
Total current liabilities	57,092,835	6,183,850
Deferred revenue	26,061	192,728
Notes payable, net of discounts of $0 and $2,033,506, respectively	10,672,265	60,746,002
Other liabilities	1,653,328	1,677,633
Total liabilities	69,444,489	68,800,213
Commitments and contingencies		
Stockholders' deficit:		
Preferred stock; $.001 par value; 5,000,000 shares authorized; no shares issued or outstanding at March 31, 2016 and December 31, 2015, respectively	—	—
Common stock; $.001 par value; 200,000,000 shares authorized; 155,505,583 and 155,649,665 shares issued and outstanding at March 31, 2016 and	155,506	155,650

December 31, 2015, respectively		
Additional paid-in capital	326,447,029	326,085,743
Accumulated deficit	(384,232,659)	(380,546,651)
Total Navidea stockholders' deficit	(57,630,124)	(54,305,258)
Noncontrolling interest	469,316	469,558
Total stockholders’ deficit	(57,160,808)	(53,835,700)
Total liabilities and stockholders’ deficit	$12,283,681	$14,964,513

See accompanying notes to consolidated financial statements (unaudited).

Navidea Biopharmaceuticals, Inc. and Subsidiaries

Consolidated Statements of Operations

(unaudited)

	Three Months Ended March 31,	
	2016	2015
Revenue:		
Lymphoseek sales revenue	$3,782,680	$1,835,422
Lymphoseek license revenue	254,050	83,333
Grant and other revenue	685,825	189,701
Total revenue	4,722,555	2,108,456
Cost of goods sold	534,929	449,057
Gross profit	4,187,626	1,659,399
Operating expenses:		
Research and development	2,659,520	3,981,288
Selling, general and administrative	4,096,660	5,494,168
Total operating expenses	6,756,180	9,475,456
Loss from operations	(2,568,554)	(7,816,057)
Other income (expense):		
Interest expense, net	(2,193,523)	(966,576)
Equity in loss of R-NAV, LLC	(12,239)	(262,227)
Change in fair value of financial instruments	1,125,359	1,727,103
Other, net	(37,292)	26,532
Total other income (expense), net	(1,117,695)	524,832
Net loss	(3,686,249)	(7,291,225)
Less loss attributable to noncontrolling interest	(241)	(100)
Deemed dividend on beneficial conversion feature of MT Preferred Stock	—	(46,000)
Net loss attributable to common stockholders	$(3,686,008)	$(7,337,125)
Loss per common share (basic and diluted)	$(0.02)	$(0.05)
Weighted average shares outstanding (basic and diluted)	155,308,094	149,794,331

See accompanying notes to consolidated financial statements (unaudited).

Navidea Biopharmaceuticals, Inc. and Subsidiaries

Consolidated Statement of Stockholders' Deficit

(unaudited)

	Preferred Stock Shares	Preferred Stock Amount	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Accumulated Deficit	Non-controlling Interest	Total Stockholders' Deficit
Balance, December 31, 2015	—	$ —	155,649,665	$155,650	$326,085,743	$(380,546,651)	$ 469,558	$(53,835,700)
Canceled forfeited restricted stock	—	—	(161,000)	(161)	161	—	—	—
Issued stock in payment of Board retainers	—	—	16,918	17	20,623	—	—	20,640
Stock compensation expense	—	—	—	—	340,502	—	—	340,502
Net loss	—	—	—	—	—	(3,686,008)	(241)	(3,686,249)
Balance, March 31, 2016	—	$ —	155,505,583	$155,506	$326,447,029	$(384,232,659)	$ 469,316	$(57,160,808)

See accompanying notes to consolidated financial statements (unaudited).

Navidea Biopharmaceuticals, Inc. and Subsidiaries

Consolidated Statements of Cash Flows

(unaudited)

	Three Months Ended March 31,	
	2016	2015
Cash flows from operating activities:		
Net loss	$(3,686,249)	$(7,291,225)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	149,590	149,822
Loss on disposal and abandonment of assets	—	5,726
Change in inventory reserve	—	120,302
Amortization of debt discount and issuance costs	72,875	212,813
Compounded interest on long term debt	824,952	—
Stock compensation expense	340,502	1,106,824
Equity in loss of R-NAV, LLC	12,239	262,227
Change in fair value of financial instruments	(1,125,359)	(1,727,103)
Issued stock to 401(k) plan for employer matching contributions	—	117,099
Other	8,401	48,971
Changes in operating assets and liabilities:		
Accounts receivable	903,147	(394,471)
Inventory	(246,030)	240,478
Prepaid expenses and other assets	193,795	20,241
Accounts payable	1,133,840	428,458
Accrued and other liabilities	4,418	673,969
Deferred revenue	(265,758)	1,916,667
Net cash used in operating activities	(1,679,637)	(4,109,202)
Cash flows from investing activities:		
Purchases of equipment	(1,847)	—
Proceeds from sales of equipment	—	20,300
Patent and trademark costs	—	(5,643)
Net cash (used in) provided by investing activities	(1,847)	14,657
Cash flows from financing activities:		
Proceeds from issuance of MT Preferred Stock and warrants	—	500,000
Proceeds from issuance of common stock	—	332
Proceeds from notes payable	—	3,000,000
Payments under capital leases	(693)	(604)
Net cash (used in) provided by financing activities	(693)	3,499,728
Net decrease in cash	(1,682,177)	(594,817)
Cash, beginning of period	7,166,260	5,479,006
Cash, end of period	$5,484,083	$4,884,189

See accompanying notes to consolidated financial statements (unaudited).

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Notes to the Consolidated Financial Statements (unaudited)

1. Summary of Significant Accounting Policies

a. Basis of Presentation: The information presented as of March 31, 2016 and for the three-month periods ended March 31, 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 March 31, 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. Navidea's investment in R-NAV, LLC (R-NAV) is being accounted for using the equity method of accounting and is therefore not consolidated.

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

(2) Notes payable: The carrying value of our debt at March 31, 2016 and December 31, 2015 primarily consists of the face amount of the notes less unamortized discounts. See Note 8. At March 31, 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 March 31, 2016, the fair value of our notes payable is approximately $63.7 million, compared to the carrying value of $60.9 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 March 31, 2016 and December 31, 2015 were included in other liabilities on the consolidated balance sheets. The assumptions used to calculate fair value as of March 31, 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 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 three-month periods ended March 31, 2016 and 2015, over 99% of Lymphoseek sales were made to Cardinal Health. As of March 31, 2016, approximately 98% 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 is being recognized on a straight-line basis over the estimated obligation period of two years.

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. See Note 7.

d. Recent Accounting Pronouncements: In March 2016, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (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.

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 Capital Royalty Partners II L.P. (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.

It appears likely that we will need to draw on the Platinum line of credit in order to maintain compliance with the $5 million liquidity covenant of the CRG Loan Agreement beginning in the second quarter of 2016. Our inability to meet the liquidity covenant would be an event of default under the CRG Loan Agreement. In addition, if we are unable to reach the 2016 annual Lymphoseek sales revenue target of $22.5 million, this would also be an event of default under the CRG Loan Agreement; however, potential shortfalls to this revenue covenant are curable by the Company depositing 2.5 times the amount of the shortfall in a bank account controlled by CRG. 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. An event of default would entitle CRG to accelerate the maturity of our indebtedness, increase the interest rate to the default rate of 18% per annum, and invoke other remedies available to it under the loan agreement and the related security agreement, which could raise substantial doubt about the Company's ability to continue as a going concern. See Notes 8 and 9.

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. We are currently in compliance with all covenants under the Platinum Loan Agreement. See Note 8.

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 $10.7 million at March 31, 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 March 31, 2016, and will continue to be measured on a recurring basis. See Note 1(b)(3).

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

Liabilities Measured at Fair Value on a Recurring Basis as of March 31, 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	$ —	$ —	$ 1,886,521	$1,886,521
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 liabilities outstanding at any time during the three-month periods ended March 31, 2016 and 2015. There were no transfers in or out of our Level 2 liabilities during the three-month periods ended March 31, 2016 or 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 March 31, 2016 and 2015 was a decrease of $1.1 million and $1.7 million, respectively.

4. Stock-Based Compensation

For the three-month periods ended March 31, 2016 and 2015, our total stock-based compensation expense, which includes reversals of expense for certain forfeited or cancelled awards, was approximately $341,000 and $1.1 million, respectively. We have not recorded any income tax benefit related to stock-based compensation in either of the three-month periods ended March 31, 2016 and 2015.

A summary of the status of our stock options as of March 31, 2016, and changes during the three-month period then ended, is presented below:

	Three Months Ended March 31, 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	366,457	0.96		
Exercised	—	—		
Canceled and Forfeited	(112,000)	1.86		
Expired	(299,000)	2.42		
Outstanding at end of period	5,392,521	$ 1.87	7.5 years	$ 104,600
Exercisable at end of period	3,337,968	$ 2.03	6.8 years	$ 101,276

A summary of the status of our unvested restricted stock as of March 31, 2016, and changes during the three-month period then ended, is presented below:

	Three Months Ended March 31, 2016	
	Number of Shares	Weighted Average Grant-Date Fair Value
Unvested at beginning of period	361,000	$ 1.69
Granted	—	—
Vested	(66,000)	1.65
Forfeited	(161,000)	1.75
Unvested at end of period	134,000	$ 1.63

During the three-month period ended March 31, 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 three-month period ended March 31, 2016, 161,000 shares of unvested restricted stock were forfeited upon termination of certain directors and an officer.

As of March 31, 2016, there was approximately $815,000 of total unrecognized compensation expense related to unvested stock-based awards, which we expect to recognize over the remaining weighted average vesting term of 1.7 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 three-month periods ended March 31, 2016 and 2015 excludes the effects of 15.1 million and 20.1 million common share equivalents, respectively, since such inclusion would be anti-dilutive. The excluded shares consist of common shares issuable upon exercise of outstanding stock options and warrants, and upon the conversion of convertible debt and convertible preferred stock.

The Company’s unvested stock awards contain nonforfeitable rights to dividends or dividend equivalents, whether paid or unpaid (referred to as “participating securities”). Therefore, the unvested stock awards are required to be included in the number of shares outstanding for both basic and diluted earnings per share calculations. However, due to our loss from continuing operations, 134,000 and 671,500 shares of unvested restricted stock for the three-month periods

ended March 31, 2016 and 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 March 31, 2016 and December 31, 2015 are as follows:

	March 31, 2016 (unaudited)	December 31, 2015
Materials	$30,000	$330,000
Work-in-process	108,518	392,457
Finished goods	938,324	275,168
Reserves	(177,906)	(344,719)
Total	$898,936	$652,906

During the three-month period ended March 31, 2015, we wrote off $120,000 of materials related to production issues. During the three-month period ended March 31, 2015, the Company used $37,000 of Lymphoseek inventory for clinical study and product development purposes.

7. Investment in R-NAV, LLC

Navidea's investment in R-NAV, LLC (R-NAV) of approximately 27% is being accounted for using the equity method of accounting. Navidea's equity in the loss of R-NAV was $12,239 and $262,227, respectively, for the three-month periods ended March 31, 2016 and 2015. Navidea's equity in the loss of R-NAV has exceeded our initial investment in R-NAV. As such, the carrying value of the Company's investment in R-NAV was $0 as of March 31, 2016 and December 31, 2015.

The Company's obligation to provide $500,000 of in-kind services to R-NAV is being recognized as those services are provided. The Company provided $12,000 and $21,000, respectively, of in-kind services during the three-month periods ended March 31, 2016 and 2015. As of March 31, 2016, the Company has $385,000 of in-kind services remaining to provide under this obligation.

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

8. 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 three-month period ended March 31, 2016, $306,000 of interest was compounded and added to the balance of the Platinum Note. As of March 31, 2016, the outstanding principal balance of the Platinum Note was approximately $8.8 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.

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 $1.9 million. Changes in the estimated fair value of the Platinum Note were decreases of $1.1 million and $1.7 million, respectively, and were recorded as non-cash changes in fair value of the conversion option during the three-month periods ended March 31, 2016 and 2015. The estimated fair value of the Platinum Note was $10.7 million as of March 31, 2016.

Capital Royalty Partners II, L.P.

In May 2015, Navidea and its subsidiary Macrophage Therapeutics, Inc., as guarantor, executed a Term Loan Agreement (the CRG Loan Agreement) with Capital Royalty Partners II L.P. (CRG) in its capacity as a lender and as control agent for other affiliated lenders party to the CRG Loan Agreement (collectively, the Lenders) in which the Lenders agreed to make a term loan to the Company in the aggregate principal amount of $50 million (the CRG Term Loan), with an additional $10 million in loans to be made available upon the satisfaction of certain conditions stated in the CRG Loan Agreement. During the three-month period ended March 31, 2016, $519,000 of interest was compounded and added to the balance of the CRG Term Loan. As of March 31, 2016, the outstanding principal balance of the CRG Term Loan was $51.8 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 has been recorded for the $1.0 million facility fee. The debt discount is being amortized as non-cash interest expense using the effective interest method over the term of the CRG Loan Agreement. As of March 31, 2016, the balance of the debt discount was $2.0 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.

On April 7, 2016, we received a notice (the First Notice) from CRG, pursuant to the CRG Loan Agreement. The First Notice claims that Events of Default have occurred under Sections 11.01(m) (alleging that a Change of Control has occurred), 11.01(e) (alleging that the Company's agreement with Platinum reported in the Company's Current Report on Form 8-K filed on March 18, 2016 constituted an amendment, modification, waiver or supplement to the Loan Agreement, dated July 25, 2012, between the Company and Platinum that required the written consent of CRG and that a subsidiary of the Company opened a bank account without notifying CRG), and 11.01(d) (alleging that the failure by the Company to notify CRG of a Default itself constitutes an Event of Default) of the Loan Agreement. The Company also learned that CRG filed an Original Petition (the Petition) in the District Court for Harris County, Texas alleging the same Events of Default as set forth in the Notice and seeking an undetermined amount of damages and a declaratory judgment that the Company is in default under the Loan Agreement and that CRG, as a result, is entitled to the remedies set forth in Section 11.02 of the Loan Agreement. In the First Notice, CRG indicated that it elected not to require the amounts due under the CRG Loan Agreement to be immediately due and payable, but claimed that the Obligations under the CRG Loan Agreement shall accrue interest at the default rate of 18% per annum until paid in full.

We did not achieve the 2015 annual Lymphoseek sales revenue target of $11 million as initially established under the CRG Loan Agreement, but in December 2015 CRG agreed to a reduction of that target to $10 million (Amendment 1) and we were able to meet that reduced target with Lymphoseek sales revenue of $10.3 million, thereby complying with the covenant. On April 22, 2016 we received an additional notice (the Second Notice) from CRG, pursuant to the CRG Loan Agreement. The Second Notice claims that Amendment 1 is invalid due to the existence of Events of Default at the time of its execution in December 2015 which were not disclosed to CRG at that time. Consequently, CRG claimed that the Company failed to satisfy Section 3(b) of Amendment 1 in order for Amendment 1 to become effective and breached Section 4(a)(iii) of Amendment 1, and as such, Amendment 1 is of no effect and the Company is bound by the 2015 annual Lymphoseek sales revenue target of $11 million as originally set forth in the CRG Loan Agreement. Since the Company' 2015 Lymphoseek sales revenue was $10.3 million, the Second Notice claims that an additional Event of Default has occurred under Section 11.01(d) of the CRG Loan Agreement.

On April 28, 2016, the Company received a further notice (the Third Notice) from CRG informing the Company that CRG commenced exercising its remedies, including with respect to cash collateral. In that regard, CRG informed the Company that it had delivered notices to exercise control of the Company's accounts pursuant to the blocked account control and pledge collateral account control agreements with CRG. On May 2, 2016, the Company successfully sought a temporary restraining order in Harris County Court, Texas, in which the court enjoined CRG from causing any further "freeze" of the Company's accounts and required CRG to restore the accounts to the position they were in prior to CRG's April 28, 2016 acts, pending a more complete review of the Company's and CRG's positions in the lawsuit in a hearing scheduled for May 19, 2016.

The Company is maintaining its position that the alleged claims do not constitute Events of Default under the CRG Loan Agreement and intends to vigorously defend against these claims. The Company continues to evaluate its options, including the possible assertion of counterclaims. However, if the Company does not prevail in these legal proceedings, CRG may invoke any and all remedies available to it under the loan agreement and the related security agreement, including acceleration of the maturity of our indebtedness, which could materially adversely affect our

ability to continue as a going concern.

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 net balance of the CRG Term Loan as a current liability as of March 31, 2016.

R-NAV, LLC

As of March 31, 2016, the outstanding principal balance of the note payable to R-NAV was $333,333 which is due in July 2016.

Summary

During the three-month periods ended March 31, 2016 and 2015, we recorded interest expense of $2.2 million and $967,000, respectively, related to our notes payable. Of these amounts, $73,000 and $213,000, respectively, related to amortization of the

debt discounts related to our notes payable. An additional $825,000 of total interest expense was compounded and added to the balance of our notes payable during the three-month period ended March 31, 2016.

9. 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 believes the suit is without merit and has filed a motion to dismiss the action. 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.

CRG Litigation

On April 7, 2016, we received a notice (the First Notice) from CRG, pursuant to the CRG Loan Agreement. The First Notice claims that Events of Default have occurred under Sections 11.01(m) (alleging that a Change of Control has occurred), 11.01(e) (alleging that the Company's agreement with Platinum reported in the Company's Current Report on Form 8-K filed on March 18, 2016 constituted an amendment, modification, waiver or supplement to the Loan Agreement, dated July 25, 2012, between the Company and Platinum that required the written consent of CRG and that a subsidiary of the Company opened a bank account without notifying CRG), and 11.01(d) (alleging that the failure by the Company to notify CRG of a Default itself constitutes an Event of Default) of the Loan Agreement. The Company also learned that CRG filed an Original Petition (the Petition) in the District Court for Harris County, Texas alleging the same Events of Default as set forth in the Notice and seeking an undetermined amount of damages and a declaratory judgment that the Company is in default under the Loan Agreement and that CRG, as a result, is entitled to the remedies set forth in Section 11.02 of the Loan Agreement. In the First Notice, CRG indicated that it elected not to require the amounts due under the CRG Loan Agreement to be immediately due and payable, but claimed that the Obligations under the CRG Loan Agreement shall accrue interest at the default rate of 18% until paid in full.

We did not achieve the 2015 annual Lymphoseek sales revenue target of $11 million as initially established under the CRG Loan Agreement, but in December 2015 CRG agreed to a reduction of that target to $10 million (Amendment 1) and we were able to meet that reduced target with Lymphoseek sales revenue of $10.3 million, thereby complying with the covenant. On April 22, 2016 we received an additional notice (the Second Notice) from CRG, pursuant to the CRG Loan Agreement. The Second Notice claims that Amendment 1 is invalid due to the existence of Events of Default at the time of its execution in December 2015 which were not disclosed to CRG at that time. Consequently, CRG claimed that the Company failed to satisfy Section 3(b) of Amendment 1 in order for Amendment 1 to become effective and breached Section 4(a)(iii) of Amendment 1, and as such, Amendment 1 is of no effect and the Company is bound by the 2015 annual Lymphoseek sales revenue target of $11 million as originally set forth in the CRG Loan Agreement. Since the Company's 2015 Lymphoseek sales revenue was $10.3 million, the Second Notice claims that an additional Event of Default has occurred under Section 11.01(d) of the CRG Loan Agreement.

On April 28, 2016, the Company received a further notice (the Third Notice) from CRG informing the Company that CRG commenced exercising its remedies, including with respect to cash collateral. In that regard, CRG informed the Company that it had delivered notices to exercise control of the Company's accounts pursuant to the blocked account control and pledge collateral account control agreements with CRG. On May 2, 2016, the Company successfully sought a temporary restraining order in Harris County Court, Texas, in which the court enjoined CRG from causing any further "freeze" of the Company's accounts and required CRG to restore the accounts to the position they were in prior to CRG's April 28, 2016 acts, pending a more complete review of the Company's and CRG's positions in the

lawsuit in a hearing scheduled for May 19, 2016.

The Company is maintaining its position that the alleged claims do not constitute Events of Default under the Loan Agreement and intends to vigorously defend against these claims. The Company continues to evaluate its options, including the possible assertion of counterclaims. However, if the Company does not prevail in these legal proceedings, CRG may invoke any and all remedies available to it under the loan agreement and the related security agreement, including acceleration of the maturity of our indebtedness, which could materially adversely affect our ability to continue as a going concern. See Notes 2 and 8.

10. Equity Instruments

During the three-month period ended March 31, 2016, we issued 16,918 shares of our common stock valued at $21,000 to a member of our Board of Directors as payment in lieu of cash for his fourth quarter 2015 compensation.

11. Stock Warrants

At March 31, 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 1 to 19 years.

In addition, at March 31, 2016, there are 300 warrants outstanding to purchase MT Common Stock. The warrants are exercisable at $2,000 per share.

12. Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases, and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. Due to the uncertainty surrounding the realization of the deferred tax assets in future tax returns, all of the deferred tax assets have been fully offset by a valuation allowance at March 31, 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 March 31, 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 March 31, 2016, tax years 2012-2015 remained subject to examination by federal and state tax authorities.

13. 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 subsidiary, NAV4694 and NAV5001 (license terminated in April 2015), and (ii) therapeutic development programs, including therapeutic applications of our Manocept platform and all development programs undertaken by Macrophage Therapeutics, Inc.

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

Three Months Ended March 31, 2016	Diagnostics	Therapeutics	Corporate	Total
Lymphoseek sales revenue:				
United States [1]	$3,771,420	$ —	$—	$3,771,420
International	11,260	—	—	11,260
Lymphoseek license revenue	254,050	—	—	254,050
Grant and other revenue	685,825	—	—	685,825
Total revenue	4,722,555	—	—	4,722,555
Cost of goods sold, excluding depreciation and amortization	494,639	—	—	494,639
Research and development expenses, excluding depreciation and amortization	2,417,720	241,800	—	2,659,520
Selling, general and administrative expenses, excluding depreciation and amortization [2]	1,012,106	(598)	2,975,850	3,987,358
Depreciation and amortization [3]	40,290	—	109,302	149,592
Loss from operations [4]	757,800	(241,202)	(3,085,152)	(2,568,554)
Other income (expense), excluding equity in the loss of R-NAV, LLC [5]	—	—	(1,105,456)	(1,105,456)
Equity in the loss of R-NAV, LLC	—	—	(12,239)	(12,239)
Net loss	757,800	(241,202)	(4,202,847)	(3,686,249)
Total assets, net of depreciation and amortization:				
United States	4,109,640	16,515	7,774,939	11,901,094
International	380,982	—	1,605	382,587
Capital expenditures	—	—	1,847	1,847

Three Months Ended March 31, 2015	Diagnostics	Therapeutics	Corporate	Total
Lymphoseek sales revenue:				
United States [1]	$1,831,022	$ —	$—	$1,831,022
International	4,400	—	—	4,400
Lymphoseek license revenue	83,333	—	—	83,333
Grant and other revenue	189,701	—	—	189,701
Total revenue	2,108,456	—	—	2,108,456
Cost of goods sold, excluding depreciation and amortization	420,551	—	—	420,551
Research and development expenses, excluding depreciation and amortization	3,890,724	86,014	—	3,976,738
Selling, general and administrative expenses, excluding depreciation and amortization [2]	2,042,175	14,366	3,320,861	5,377,402
Depreciation and amortization [3]	33,056	—	116,766	149,822
Loss from operations [4]	(4,278,050)	(100,380)	(3,437,627)	(7,816,057)
Other income (expense), excluding equity in the loss of R-NAV, LLC [5]	—	—	787,059	787,059

Equity in the loss of R-NAV, LLC	—	—	(262,227)	(262,227)
Net loss	(4,278,050)	(100,380)	(2,912,795)	(7,291,225)
Total assets, net of depreciation and amortization:				
United States	3,333,851	7,409	7,077,673	10,418,933
International	496,311	—	2,665	498,976
Capital expenditures	—	—	—	—

(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 ($40,290 and $28,506 for the three-month periods ended March 31, 2016 and 2015), research and development ($0 and $4,550 for the three-month periods ended March 31, 2016 and 2015), and selling, general and administrative expenses ($109,302 and $116,765 for the three-month periods ended March 31, 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.

14. Supplemental Disclosure for Statements of Cash Flows

During the three-month periods ended March 31, 2016 and 2015, we paid interest aggregating $1.3 million and $701,000, respectively. During the three-month period ended March 31, 2015, we issued 68,157 shares of our common stock as a matching contribution to our 401(k) Plan which were valued at $117,000.

15. Subsequent Events

a. CRG Notice of Default: On April 7, 2016, we received a notice (the First Notice) from CRG, pursuant to the CRG Loan Agreement. The First Notice claims that Events of Default have occurred under Sections 11.01(m) (alleging that a Change of Control has occurred), 11.01(e) (alleging that the Company's agreement with Platinum reported in the Company's Current Report on Form 8-K filed on March 18, 2016 constituted an amendment, modification, waiver or supplement to the Loan Agreement, dated July 25, 2012, between the Company and Platinum that required the written consent of CRG and that a subsidiary of the Company opened a bank account without notifying CRG), and 11.01(d) (alleging that the failure by the Company to notify CRG of a Default itself constitutes an Event of Default) of the Loan Agreement. The Company also learned that CRG filed an Original Petition (the Petition) in the District Court for Harris County, Texas alleging the same Events of Default as set forth in the Notice and seeking an undetermined amount of damages and a declaratory judgment that the Company is in default under the Loan Agreement and that CRG, as a result, is entitled to the remedies set forth in Section 11.02 of the Loan Agreement. In the First Notice, CRG indicated that it elected not to require the amounts due under the CRG Loan Agreement to be immediately due and payable, but claimed that the Obligations under the CRG Loan Agreement shall accrue interest at a rate equal to the Default Rate of 18% per annum until paid in full.

We did not achieve the 2015 annual Lymphoseek sales revenue target of $11 million as initially established under the CRG Loan Agreement, but in December 2015 CRG agreed to a reduction of that target to $10 million (Amendment 1) and we were able to meet that reduced target with Lymphoseek sales revenue of $10.3 million, thereby complying with the covenant. On April 22, 2016 we received an additional notice (the Second Notice) from CRG, pursuant to the CRG Loan Agreement. The Second Notice claims that Amendment 1 is invalid due to the existence of Events of Default at the time of its execution in December 2015 which were not disclosed to CRG at that time. Consequently, CRG claimed that the Company failed to satisfy Section 3(b) of Amendment 1 in order for Amendment 1 to become effective and breached Section 4(a)(iii) of Amendment 1, and as such, Amendment 1 is of no effect and the Company is bound by the 2015 annual Lymphoseek sales revenue target of $11 million as originally set forth in the CRG Loan Agreement. Since the Company' 2015 Lymphoseek sales revenue was $10.3 million, the Second Notice claims that an additional Event of Default has occurred under Section 11.01(d) of the CRG Loan Agreement.

On April 28, 2016, the Company received a further notice (the Third Notice) from CRG informing the Company that CRG commenced exercising its remedies, including with respect to cash collateral. In that regard, CRG informed the Company that it had delivered notices to exercise control of the Company's accounts pursuant to the blocked account control and pledge collateral account control agreements with CRG. On May 2, 2016, the Company successfully sought a temporary restraining order in Harris County Court, Texas, in which the court enjoined CRG from causing any further "freeze" of the Company's accounts and required CRG to restore the accounts to the position they were in prior to CRG's April 28, 2016 acts, pending a more complete review of the Company's and CRG's positions in the

lawsuit in a hearing scheduled for May 19, 2016.

The Company is maintaining its position that the alleged claims do not constitute Events of Default under the Loan Agreement and intends to vigorously defend against these claims. The Company continues to evaluate its options, including the possible assertion of counterclaims. However, if the Company does not prevail in these legal proceedings, CRG may invoke any and all remedies available to it under the loan agreement and the related security agreement, including acceleration of the maturity of our indebtedness, which could materially adversely affect our ability to continue as a going concern.

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 net balance of the CRG Term Loan as a current liability as of March 31, 2016.

b. Termination of CEO: 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 believes that it has meritorious defenses to the claims by Mr. Gonzalez and intends to vigorously defend its position.

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;
- 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. 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.

Navidea remains committed to realizing the full potential of Lymphoseek. In mid-2015, we deployed our own field sales force and began implementing a new strategy to accelerate the strong year-over-year growth of this product. The Company believes that the resources being devoted to drive Lymphoseek sales will lead to positive cash flows and profitability. We are focused on expanding the market for Lymphoseek in all relevant markets.

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 increasingly offset by growing Lymphoseek revenue. In particular, substantial progress on the Manocept platform has resulted in several promising opportunities, including our R-NAV, LLC venture which began in July 2014, the formation of Macrophage Therapeutics, Inc. in January 2015, and Macrophage Therapeutics' research collaboration agreement with BIND Therapeutics, Inc. executed in June 2015.

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.

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. Our partner, SpePharm AG (an affiliate of Norgine BV), is currently performing the customary pre-launch market access activities to support commercial launch in the EU later in 2016. Concurrently, we are completing manufacturing validation activities on a finished drug product contract manufacturing facility to support the Company’s supply chain, primarily in Europe.

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.

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, Kaposi's sarcoma (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 Lymphoseek 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 Lymphoseek. 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 Lymphoseek. The addition of this new route of administration would enable further development of Lymphoseek 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 Lymphoseek label 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 Lymphoseek 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 Lymphoseek.

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 providing for up to $1.7 million 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 will be released in two parts, which together have the potential to provide a total of $1.7 million in resources over two and a half years to achieve the specific aims and objectives of the grant. The first part will provide $225,000 to support preclinical animal studies and to support activities needed to

prepare for the Phase 1/2 clinical study. The second part of the award will support the Phase 1/2 study, the results from which are expected to confirm the safety and effectiveness of Tc 99m tilmanocept to identify skeletal joint inflammation due to RA.

Our plans in RA include a Phase 1 pilot trial evaluating subcutaneous injection of Lymphoseek in active RA subjects expected to begin in the second quarter of 2016. In conjunction with the agreed submission of an IND amendment for IV administration of Lymphoseek to the FDA, we expect to initiate a multi-center Phase 1/2 registrational trial employing IV administration to evaluate Lymphoseek for the primary diagnosis of RA and to aid in the differential diagnosis of RA from other types of inflammatory arthritis during the second half 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 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 have been dosed subcutaneously at Massachusetts General Hospital and results are being analyzed and prepared 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. Our plans are to initiate a Phase 1/2 clinical study in KS during the second half of 2016.

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. NAV1800 was originally intended to use a monoclonal antibody as an aid in identifying TAG-72, a specific factor associated with a primary tumor, ascertaining tumor margins,

or determining the extent and location of occult and metastatic tumor in patients with solid tumor cancers, such as colorectal cancer, ovarian cancer, or endometrial cancer. The detection of clinically occult tumor was originally intended to provide the surgeon with a more accurate assessment of the extent and location of disease, and therefore impact the surgical and therapeutic management of the patient.

Over the last few years, our commercial evaluation of new clinical data has caused us to question the viability of the monoclonal antibody initiative as it was originally envisioned. During the same time period, 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, we cannot assure you 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 June 2015, BIND Therapeutics, Inc. (BIND), an early clinical-stage nanomedicine company developing targeted and programmable therapeutics called Accurins™, and MT entered into a research collaboration to engineer Accurins with the Manocept targeting platform. This agreement was renewed in February 2016 to extend the agreement through February 2017. Disease-associated macrophages generally play a pro-tumoral role and are immunosuppressive, preventing the immune system from mounting an attack on tumor cells. Based on the expression of CD206 mannose receptors on disease-associated macrophages, BIND and MT plan to consider joint research programs that may be capable of concentrating various therapeutic payloads to the tumor microenvironment.

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 antibiotic, 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 – Immuno-Therapeutics 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 the University of California, San Francisco (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 two investor update conference calls held in April and May2016, 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.

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. We cannot assure you 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 believes the suit is without merit and has filed a motion to dismiss the action. While it is not possible to determine with any degree of certainty the ultimate outcome of this legal proceeding, including making a determination of liability, we believe that we have meritorious defenses with respect to the claims asserted against us and intend to vigorously defend our position.

NAV5001 (In-License Terminated)

NAV5001 is an iodine-123 (I-123) labeled SPECT imaging agent being developed as an aid in the diagnosis of Parkinson's disease (PD) and other movement disorders, with potential use as a diagnostic aid in dementia. The agent binds to the dopamine transporter

(DAT) on the cell surface of dopaminergic neurons in the striatum and substantia nigra regions of the brain. Loss of these neurons is a hallmark of PD. In addition to its potential use as an aid in the differential diagnosis of PD and movement disorders, NAV5001 may also be useful in the diagnosis of Dementia with Lewy Bodies, one of the most common forms of dementia after AD.

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

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

Outlook

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 focuses 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 $2.7 million and $4.0 million in total on research and development activities during the three-month periods ended March 31, 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:

	Three Months Ended	
	March 31,	
Development Program *	2016	2015
Lymphoseek	$554,692	$639,796
Manocept Platform	184,344	164,671
Macrophage Therapeutics	187,583	28,027
NAV4694	564,558	1,206,333
NAV5001	54,424	139,677

* Certain development program expenditures were offset by grant reimbursement revenues totaling $608,000 and $114,000 during the three-month periods ended March 31, 2016 and 2015, respectively.

We expect to continue the advancement of our efforts with Lymphoseek and our Manocept platform during 2016. 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 that 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, perhaps by as much as 30%. This estimate excludes charges related to our subsidiary, Macrophage Therapeutics, Inc., which are currently expected to be funded separately. In addition, these estimates include carrying costs for NAV4694 only through mid-year.

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 share 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. 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 intended for sale 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. We cannot assure you 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. We cannot assure you 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.

The Company projects that its total revenue for 2016, including Lymphoseek product sales revenue, license revenue, grant and other revenue, will be in the range of $23 million to $25 million. Gross margins on Lymphoseek product sales are expected to continue to remain at approximately 80% in the coming quarters. Based on our current projections, we expect total operating expenses for 2016 to be between $21.5 million and $23.5 million, excluding charges related to our subsidiary, Macrophage Therapeutics, Inc., which are currently expected to be funded separately. As a result of our revenue and margin expectations for 2016, coupled with our expectations of operating expenses for the year, we also expect to reach cash flow breakeven on an operating or per-share basis in the second half of 2016.

Results of Operations

Three Months Ended March 31, 2016 and 2015

Lymphoseek Sales and Margins. Net sales of Lymphoseek were $3.8 million during the first quarter of 2016, compared to $1.8 million during the same period of 2015. The increase was primarily the result of continued efforts to increase sales through increased adoption of Lymphoseek. Gross margins on net sales were 86% and 76% for the first quarters of 2016 and 2015, respectively. Cost of goods sold in the first quarter of 2015 included net inventory losses of $80,000 related to a production issue. Excluding the one-time inventory charge, gross margin for the first quarter of 2015 would have been 80%. 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 the University of California, San Diego (UCSD).

Lymphoseek License Revenue. During the first quarters of 2016 and 2015, we recognized $254,000 and $83,000, respectively, of the $2.0 million non-refundable upfront payment received by the Company related to the Lymphoseek license and distribution agreement for Europe, which the Company is recognizing on a straight-line basis over two years.

Grant and Other Revenue. During the first quarter of 2016, we recognized $686,000 of grant and other revenue as compared to $190,000 in the first quarter of 2015. Grant revenue during the first quarter of 2016 was primarily related to SBIR grants from the NIH supporting NAV4694, Lymphoseek and Manocept development. Grant revenue during the first quarter of 2015 was primarily related to SBIR grants from the NIH supporting NAV4694 and Lymphoseek development. Grant and other revenue for the first quarters of 2016 and 2015 also included $23,000 and $51,000, respectively, of revenue related to services provided to R-NAV for Manocept development.

Research and Development Expenses. Research and development expenses decreased $1.3 million, or 33%, to $2.7 million during the first quarter of 2016 from $4.0 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 $642,000 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 NAV5001 development costs of $85,000 including decreased clinical trial costs and manufacturing-related activities; and (iii) decreased Lymphoseek development costs of $85,000 including decreased manufacturing-related activities offset by increased regulatory costs, clinical trial costs, and preclinical testing; offset by (iv) increased therapeutics development costs of $160,000 including increased manufacturing-related activities and preclinical testing. The net decrease in research and development expenses also included decreased compensation including incentive-based awards and other expenses related to net decreased headcount of $658,000 following the first quarter 2015 reduction in force coupled with decreased travel, office and other support costs of $31,000.

Selling, General and Administrative Expenses. Selling, general and administrative expenses decreased $1.4 million, or 25%, to $4.1 million during the first quarter of 2016 from $5.5 million during the same period in 2015. The net decrease was primarily due to decreased general and administrative headcount of $1.2 million following the first quarter 2015 reduction in force coupled with decreased costs for contracted medical science liaisons, business development consulting services, market development expenses related to Lymphoseek, and license fees, offset by increased commercial and medical headcount coupled with increased legal and professional services.

Other Income (Expense). Other expense, net, was $1.1 million during the first quarter of 2016 as compared to other expense, net of $525,000 during the same period in 2015. Interest expense, net increased $1.2 million to $2.2 million during the first quarter of 2016 from $967,000 for the same period in 2015, primarily due 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 interest rates related to the Platinum Note in 2016 versus 2015. Of this interest expense, $73,000 and $213,000 in the first quarter 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 $825,000 of this interest expense was compounded and added to the balance of our notes payable during the first quarter of 2016. For the first quarters of 2016 and 2015, we recorded non-cash income of $1.1 million and $1.7 million, respectively, related to changes in the estimated fair value of financial instruments. During the first quarters of 2016 and 2015, we recorded non-cash equity in the loss of R-NAV of $12,000 and $262,000, respectively.

Liquidity and Capital Resources

Cash balances decreased to $5.5 million at March 31, 2016 from $7.2 million at December 31, 2015. The net decrease was primarily due to cash used to fund our operations of $1.7 million.

As of the time of filing this report, it appears likely that we will need to draw on the Platinum line of credit in order to maintain compliance with the $5 million liquidity covenant of the CRG Loan Agreement beginning in the second quarter of 2016. Our inability to meet the liquidity covenant would be an event of default under the CRG Loan Agreement. In addition, if we are unable to reach the 2016 annual Lymphoseek sales revenue target of $22.5 million, this would also be an event of default under the CRG Loan Agreement; however, potential shortfalls to this revenue covenant are curable by the Company depositing 2.5 times the amount of the shortfall in a bank account controlled by CRG. 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. An event of default would entitle CRG to accelerate the maturity of our indebtedness, increase the interest rate to the default rate of 18% per annum, and invoke other remedies available to it under the loan agreement and the related security agreement, which could raise substantial doubt about the Company’s ability to continue as a going concern.

On April 7, 2016, we received a notice (the First Notice) from CRG, pursuant to the CRG Loan Agreement. The First Notice claims that Events of Default have occurred under Sections 11.01(m) (alleging that a Change of Control has occurred), 11.01(e) (alleging that the Company’s agreement with Platinum reported in the Company’s Current Report on Form 8-K filed on March 18, 2016 constituted an amendment, modification, waiver or supplement to the Loan Agreement, dated July 25, 2012, between the Company and Platinum that required the written consent of CRG and that a subsidiary of the Company opened a bank account without notifying CRG), and 11.01(d) (alleging that the failure by the Company to notify CRG of a Default itself constitutes an Event of Default) of the Loan Agreement. The Company also learned that CRG filed an Original Petition (the Petition) in the District Court for Harris County, Texas alleging the same Events of Default as set forth in the Notice and seeking an undetermined amount of damages and a declaratory judgment that the Company is in default under the Loan Agreement and that CRG, as a result, is entitled to the remedies set forth in Section 11.02 of the Loan Agreement. In the First Notice, CRG indicated that it elected not to require the amounts due under the CRG Loan Agreement to be immediately due and payable, but claimed that the Obligations under the CRG Loan Agreement shall accrue interest at the default rate of 18% until paid in full.

We did not achieve the 2015 annual Lymphoseek sales revenue target of $11 million as initially established under the CRG Loan Agreement, but in December 2015 CRG agreed to a reduction of that target to $10 million (Amendment 1) and we were able to meet that reduced target with Lymphoseek sales revenue of $10.3 million, thereby complying with the covenant. On April 22, 2016 we received an additional notice (the Second Notice) from CRG, pursuant to the CRG Loan Agreement. The Second Notice claims that Amendment 1 is invalid due to the existence of Events of Default at the time of its execution in December 2015 which were not disclosed to CRG at that time. Consequently, CRG claimed that the Company failed to satisfy Section 3(b) of Amendment 1 in order for Amendment 1 to become effective and breached Section 4(a)(iii) of Amendment 1, and as such, Amendment 1 is of no effect and the Company is bound by the 2015 annual Lymphoseek sales revenue target of $11 million as originally set forth in the CRG Loan Agreement. Since the Company' 2015 Lymphoseek sales revenue was $10.3 million, the Second Notice claims that an additional Event of Default has occurred under Section 11.01(d) of the CRG Loan Agreement.

On April 28, 2016, the Company received a further notice (the Third Notice) from CRG informing the Company that CRG commenced exercising its remedies, including with respect to cash collateral. In that regard, CRG informed the Company that it had delivered notices to exercise control of the Company's accounts pursuant to the blocked account control and pledge collateral account control agreements with CRG. On May 2, 2016, the Company successfully sought a temporary restraining order in Harris County Court, Texas, in which the court enjoined CRG from causing any further "freeze" of the Company's accounts and required CRG to restore the accounts to the position they were in prior to CRG's April 28, 2016 acts, pending a more complete review of the Company's and CRG's positions in the lawsuit in a hearing scheduled for May 19, 2016.

The Company is maintaining its position that the alleged claims do not constitute Events of Default under the Loan Agreement and intends to vigorously defend against these claims. The Company continues to evaluate its options, including the possible assertion of counterclaims. However, if the Company does not prevail in these legal proceedings, CRG may invoke any and all remedies available to it under the loan agreement and the related security agreement, including acceleration of the maturity of our indebtedness, which could materially adversely affect our ability to continue as a going concern. 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 net balance of the CRG Term Loan as a current liability as of March 31, 2016.

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. We are currently in compliance with all covenants under the Platinum Loan Agreement.

As of March 31, 2016, $27.3 million was still immediately available under the Platinum credit facility, which was reaffirmed by Platinum in March 2016. We believe that our current cash balance, our credit facility with Platinum, our projected revenue derived from sales of Lymphoseek, our ability to control expenses, the potential for partnership funding, the potential to access debt or royalty instruments, and the potential to access capital markets through our shelf registration (though we have no current intention to raise additional equity capital using the shelf registration), provide us with adequate financial resources to continue to fund our business plan for the foreseeable future and enable us to reach cash flow breakeven from operations in the second half of 2016.

Operating Activities. Cash used in operations decreased $2.4 million to $1.7 million during the first quarter of 2016 compared to $4.1 million used during the same period in 2015.

Accounts and other receivables decreased to $2.8 million at March 31, 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.

Inventory levels increased to $899,000 at March 31, 2016 from $653,000 at December 31, 2015, primarily due to finished goods inventory produced offset by finished goods inventory sold. We expect inventory levels to increase during the remainder of 2016 as we produce additional Lymphoseek inventory to build our safety stock levels and meet increasing demand.

Prepaid expenses and other current assets decreased to $853,000 at March 31, 2016 from $1.1 million at December 31, 2015, primarily due to amortization of prepaid insurance.

Accounts payable increased to $2.9 million at March 31, 2016 from $1.8 million at December 31, 2015, primarily due to net increased payables due to NAV4694, Lymphoseek, and legal and professional services vendors, offset by net decreased payables due to regulatory and commercial vendors. Accrued liabilities and other current liabilities increased slightly to $3.1 million at March 31, 2016 from $3.0 million at December 31, 2015, primarily due to increased accruals for legal and professional services, Lymphoseek development costs, and Macrophage Therapeutics costs, offset by decreased accruals for NAV4694 development costs. Our payable and accrual balances will continue to fluctuate but will likely decrease overall as we continue to decrease our level of development activity related to NAV4694, offset by planned increases in commercial activity related to Lymphoseek and development activity related to the Manocept platform.

Investing Activities. Investing activities used $2,000 during the first quarter of 2016 compared to providing $15,000 during the same period in 2015. Capital expenditures of $2,000 during the first quarter of 2016 were primarily for computer equipment. Proceeds from sales of equipment of $20,000 were offset by patent and trademark costs of $6,000 during the first quarter 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 $1,000 during the first quarter of 2016 compared to providing $3.5 million during the same period in 2015. The $3.5 million provided by financing activities in the first quarter of 2015 consisted primarily of proceeds from draws under the Platinum credit facility of $3.0 million and proceeds from issuance of MT Preferred Stock of $500,000.

Investment in Macrophage Therapeutics, Inc.

In December 2015 and May 2016, Platinum contributed a total of $200,000 to Macrophage Therapeutics, Inc. MT is not obligated to provide anything in return, although it is likely that the MT Board will ultimately authorize some form of compensation to Platinum. As such, the Company has recorded a current liability until the form of compensation has been determined.

Investment in R-NAV, LLC

Navidea's investment in R-NAV, LLC (R-NAV) is being accounted for using the equity method of accounting. Navidea's equity in the loss of R-NAV was $12,000 for the three-month period ended March 31, 2016. The Company's obligation to provide $500,000 of in-kind services to R-NAV is being recognized as those services are provided. The Company provided $12,000 of in-kind services during the three-month period ended March 31, 2016. As of March 31, 2016, the Company has $385,000 of in-kind services remaining to provide under this obligation. As of March 31, 2016, the outstanding principal balance of the note payable to R-NAV was $333,333. The final payment of $333,333 is due in July 2016.

Capital Royalty Group Debt

In May 2015, Navidea and its subsidiary Macrophage Therapeutics, Inc., as guarantor, executed a Term Loan Agreement (the CRG Loan Agreement) with Capital Royalty Partners II L.P. in its capacity as a lender and as control agent for other affiliated lenders party to the CRG Loan Agreement (collectively, the Lenders) in which the Lenders agreed to make a term loan to the Company in the aggregate principal amount of $50 million (the CRG Term Loan), with an additional $10 million in loans to be made available upon the satisfaction of certain conditions stated in the CRG Loan Agreement. During the three-month period ended March 31, 2016, $519,000 of interest was compounded and added to the balance of the CRG Term Loan. As of March 31, 2016, the outstanding principal balance of the CRG Term Loan was $51.8 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.

On April 7, 2016, we received a notice (the First Notice) from CRG, pursuant to the CRG Loan Agreement. The First Notice claims that Events of Default have occurred under Sections 11.01(m) (alleging that a Change of Control has occurred), 11.01(e) (alleging that the Company’s agreement with Platinum reported in the Company’s Current Report

on Form 8-K filed on March 18, 2016 constituted an amendment, modification, waiver or supplement to the Loan Agreement, dated July 25, 2012, between the Company and Platinum that required the written consent of CRG and that a subsidiary of the Company opened a bank account without notifying CRG), and 11.01(d) (alleging that the failure by the Company to notify CRG of a Default itself constitutes an Event of Default) of the Loan Agreement. The Company also learned that CRG filed an Original Petition (the Petition) in the District Court for Harris County, Texas alleging the same Events of Default as set forth in the Notice and seeking an undetermined amount of damages and a declaratory judgment that the Company is in default under the Loan Agreement and that CRG, as a result, is entitled to the remedies set forth in Section 11.02 of the Loan Agreement. In the First Notice, CRG indicated that it elected not to require the amounts due under the CRG Loan Agreement to be immediately due and payable, but claimed that the Obligations under the CRG Loan Agreement shall accrue interest at the default rate of 18% per annum until paid in full.

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The Company is maintaining its position that the alleged claims do not constitute Events of Default under the Loan Agreement and intends to vigorously defend against these claims. The Company continues to evaluate its options, including the possible assertion of counterclaims. However, if the Company does not prevail in these legal proceedings, CRG may invoke any and all remedies available to it under the loan agreement and the related security agreement, including acceleration of the maturity of our indebtedness, which could materially adversely affect our ability to continue as a going concern.

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 quarter of 2016, $306,000 of interest was compounded and added to the balance of the Platinum Note. As of March 31, 2016, the outstanding principal balance of the Platinum Note was approximately $8.8 million, consisting of $7.7 million of draws and $1.1 million of compounded interest, with $27.3 million still available under the credit facility, which was reaffirmed by Platinum in March 2016.

Summary

Our future liquidity and capital requirements will depend on a number of factors, including 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.

As of the time of filing this report, it appears likely that we will need to draw on the Platinum line of credit in order to maintain compliance with the $5 million liquidity covenant of the CRG Loan Agreement beginning in the second

quarter of 2016. Our inability to meet the liquidity covenant would be an event of default under the CRG Loan Agreement. In addition, if we are unable to reach the 2016 annual Lymphoseek sales revenue target of $22.5 million, this would also be an event of default under the CRG L