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 overa