

NAVIDEA BIOPHARMACEUTICALS, INC.
Form 10-Q
May 11, 2015

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q
(Mark One)

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

For the quarterly period ended March 31, 2015

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

For the transition period from to

Commission File Number: 001-35076

NAVIDEA BIOPHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware

31-1080091

(State or other jurisdiction of incorporation or
organization)

(IRS Employer Identification No.)

5600 Blazer Parkway, Suite 200, Dublin, Ohio

43017-7550

(Address of principal executive offices)

(Zip Code)

(614) 793-7500

(Registrant's telephone number, including area code)

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes No

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12-b-2 of the Act.)

Yes No

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date: 150,730,438 shares of common stock, par value \$.001 per share (as of the close of business on May 1, 2015).

NAVIDEA BIOPHARMACEUTICALS, INC. and SUBSIDIARIES

INDEX

PART I – Financial Information

Item 1.	Financial Statements	<u>3</u>
	Consolidated Balance Sheets as of March 31, 2015 (unaudited) and December 31, 2014	<u>3</u>
	Consolidated Statements of Operations for the Three-Month Periods Ended March 31, 2015 and March 31, 2014 (unaudited)	<u>5</u>
	Consolidated Statement of Stockholders’ Deficit for the Three-Month Period Ended March 31, 2015 (unaudited)	<u>6</u>
	Consolidated Statements of Cash Flows for the Three-Month Periods Ended March 31, 2015 and March 31, 2014 (unaudited)	<u>7</u>
	Notes to the Consolidated Financial Statements (unaudited)	<u>8</u>
Item 2.	Management’s Discussion and Analysis of Financial Condition and Results of Operations	<u>17</u>
	Forward-Looking Statements	<u>17</u>
	The Company	<u>17</u>
	Product Line Overview	<u>18</u>
	Outlook	<u>21</u>
	Results of Operations	<u>23</u>
	Liquidity and Capital Resources	<u>25</u>
	Recent Accounting Pronouncements	<u>25</u>
	Critical Accounting Policies	<u>28</u>
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	<u>30</u>
Item 4.	Controls and Procedures	<u>30</u>
PART II – Other Information		
Item 1A.	Risk Factors	<u>32</u>
Item 6.	Exhibits	<u>33</u>

PART I – FINANCIAL INFORMATION

Item 1. Financial Statements

Navidea Biopharmaceuticals, Inc. and Subsidiaries
Consolidated Balance Sheets

ASSETS	March 31, 2015 (unaudited)	December 31, 2014
Current assets:		
Cash	\$4,884,189	\$5,479,006
Accounts receivable	1,211,015	816,544
Inventory, net	571,605	932,385
Prepaid expenses and other	1,350,969	1,371,210
Total current assets	8,017,778	8,599,145
Property and equipment	3,980,470	4,124,028
Less accumulated depreciation and amortization	1,631,190	1,614,320
	2,349,280	2,509,708
Patents and trademarks	212,147	219,558
Less accumulated amortization	41,091	38,725
	171,056	180,833
Investment in R-NAV, LLC	—	241,575
Other assets	379,795	388,919
Total assets	\$10,917,909	\$11,920,180

Continued

Navidea Biopharmaceuticals, Inc. and Subsidiaries
Consolidated Balance Sheets, continued

LIABILITIES AND STOCKHOLDERS' DEFICIT	March 31, 2015 (unaudited)	December 31, 2014
Current liabilities:		
Accounts payable	\$ 1,905,957	\$ 1,477,499
Accrued liabilities and other	3,898,019	3,234,120
Deferred revenue, current	1,000,000	—
Notes payable, current, net of discounts of \$816,539 and \$829,019, respectively	6,092,442	4,383,472
Total current liabilities	12,896,418	9,095,091
Deferred revenue	916,667	—
Notes payable, net of discounts of \$1,339,596 and \$1,530,804, respectively	29,306,751	29,539,135
Other liabilities	3,161,885	3,089,420
Total liabilities	46,281,721	41,723,646
Commitments and contingencies		
Stockholders' deficit:		
Preferred stock; \$.001 par value; 5,000,000 shares authorized; 4,519 Series B shares issued and outstanding at March 31, 2015 and December 31, 2014, respectively	4	4
Common stock; \$.001 par value; 200,000,000 shares authorized; 150,610,860 and 150,200,259 shares issued and outstanding at March 31, 2015 and December 31, 2014, respectively	150,611	150,200
Additional paid-in capital	324,277,768	323,030,301
Accumulated deficit	(360,275,096)	(352,983,971)
Total Navidea stockholders' deficit	(35,846,713)	(29,803,466)
Noncontrolling interest	482,901	—
Total stockholders' deficit	(35,363,812)	(29,803,466)
Total liabilities and stockholders' deficit	\$ 10,917,909	\$ 11,920,180

See accompanying notes to consolidated financial statements (unaudited).

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

	Three Months Ended	
	March 31,	
	2015	2014
Revenue:		
Lymphoseek sales revenue	\$1,835,422	\$626,631
Lymphoseek license revenue	83,333	—
Grant and other revenue	189,701	125,173
Total revenue	2,108,456	751,804
Cost of goods sold	449,057	193,220
Gross profit	1,659,399	558,584
Operating expenses:		
Research and development	3,981,288	5,226,794
Selling, general and administrative	5,494,168	3,910,833
Total operating expenses	9,475,456	9,137,627
Loss from operations	(7,816,057)	(8,579,043)
Other income (expense):		
Interest expense, net	(966,576)	(937,045)
Equity in loss of R-NAV, LLC	(262,227)	—
Change in fair value of financial instruments	1,727,103	392,483
Loss on extinguishment of debt	—	(2,610,196)
Other, net	26,532	(6,752)
Total other income (expense), net	524,832	(3,161,510)
Net loss	(7,291,225)	(11,740,553)
Net loss attributable to noncontrolling interest	(100)	—
Deemed dividend on beneficial conversion feature of MT Preferred Stock	(46,000)	—
Net loss attributable to common stockholders	\$(7,337,125)	\$(11,740,553)
Loss per common share (basic and diluted)	\$(0.05)	\$(0.08)
Weighted average shares outstanding (basic and diluted)	149,794,331	144,783,351

See accompanying notes to consolidated financial statements (unaudited).

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

	Preferred Stock Shares	Amount	Common Stock Shares	Amount	Additional Paid-In Capital	Accumulated Deficit	Non-controlling Interest	Total Stockholders' Deficit
Balance, December 31, 2014	4,519	\$4	150,200,259	\$150,200	\$323,030,301	\$(352,983,971)	\$—	\$(29,803,466)
Issued restricted stock	—	—	332,000	332	—	—	—	332
Canceled forfeited restricted stock	—	—	(18,750)	(19)	19	—	—	—
Canceled stock to pay employee tax obligations	—	—	(7,645)	(7)	7	—	—	—
Issued stock in payment of Board retainers	—	—	36,839	37	69,586	—	—	69,623
Issued stock to 401(k) plan	—	—	68,157	68	117,031	—	—	117,099
Stock compensation expense	—	—	—	—	1,106,824	—	—	1,106,824
Net loss	—	—	—	—	—	(7,291,125)	(100)	(7,291,225)
Issuance of MT Preferred Stock, net of deemed dividend on beneficial conversion feature	—	—	—	—	(46,000)	—	483,001	437,001
Balance, March 31, 2015	4,519	\$4	150,610,860	\$150,611	\$324,277,768	\$(360,275,096)	\$482,901	\$(35,363,812)

See accompanying notes to consolidated financial statements (unaudited).

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

	Three Months Ended March 31,	
	2015	2014
Cash flows from operating activities:		
Net loss	\$(7,291,225)	\$(11,740,553)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	149,822	111,270
Loss on disposal and abandonment of assets	5,726	10,866
Change in inventory reserve	120,302	—
Amortization of debt discount and issuance costs	212,813	241,827
Stock compensation expense	1,106,824	693,203
Equity in loss of R-NAV, LLC	262,227	—
Change in fair value of financial instruments	(1,727,103)	(392,483)
Loss on extinguishment of debt	—	2,610,196
Issued stock to 401(k) plan for employer matching contributions	117,099	—
Other	48,971	—
Changes in operating assets and liabilities:		
Accounts receivable	(394,471)	563,888
Inventory	240,478	118,521
Prepaid expenses and other assets	20,241	78,533
Accounts payable	428,458	3,901
Accrued and other liabilities	673,969	(1,471,562)
Deferred revenue	1,916,667	—
Net cash used in operating activities	(4,109,202)	(9,172,393)
Cash flows from investing activities:		
Purchases of equipment	—	(985,578)
Proceeds from sales of equipment	20,300	—
Patent and trademark costs	(5,643)	(7,055)
Net cash provided by (used in) investing activities	14,657	(992,633)
Cash flows from financing activities:		
Proceeds from issuance of MT Preferred Stock and warrants	500,000	—
Proceeds from issuance of common stock and short swing profits	332	54,674
Payment of tax withholdings related to stock-based compensation	—	(70,914)
Proceeds from notes payable	3,000,000	30,000,000
Payment of debt-related costs	—	(1,750,770)
Principal payments on notes payable	—	(25,000,000)
Payments under capital leases	(604)	(527)
Net cash provided by financing activities	3,499,728	3,232,463
Net decrease in cash	(594,817)	(6,932,563)
Cash, beginning of period	5,479,006	32,939,026
Cash, end of period	\$4,884,189	\$26,006,463

See accompanying notes to consolidated financial statements (unaudited).

Notes to the Consolidated Financial Statements (unaudited)

1. Summary of Significant Accounting Policies

Basis of Presentation: The information presented as of March 31, 2015 and for the three-month periods ended March 31, 2015 and 2014 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, 2015 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, 2014, 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 is being accounted for using the equity method of accounting and is therefore not consolidated.

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 2.

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

- (1) Cash, accounts receivable, 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, 2015 and December 31, 2014 primarily consists of the face amount of the notes less unamortized discounts. See Note 8. At March 31, 2015 and December 31, 2014, 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 probability-weighted Monte Carlo simulation. These valuation methods include Level 3 inputs such as the estimated current market interest rate for similar instruments with similar creditworthiness. For the debt recorded at fair value, unrealized gains and losses on the fair value of

the debt are classified in other expenses as a change in the fair value of financial instruments in the consolidated statements of operations. At March 31, 2015, the fair value of our notes payable is approximately \$39.3 million. 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, 2015 were included in other liabilities on the (3) consolidated balance sheets. No derivative liabilities were outstanding as of December 31, 2014. The assumptions used to calculate fair value as of March 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 9.

Revenue Recognition: We currently generate revenue primarily from sales of Lymphoseek. Our standard shipping terms are FOB shipping point, and title and risk of loss passes to the customer upon delivery to a carrier for c.shipment from Cardinal Health's national distribution center to another point of destination. 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.

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

We also earn revenues related to our licensing and distribution agreements. The terms of these agreements may include payment to us of non-refundable upfront license fees, funding or reimbursement of research and development efforts, milestone payments if specified objectives are achieved, and/or royalties on product sales. We evaluate all deliverables within an arrangement to determine whether or not they provide value on a stand-alone basis. We recognize a contingent milestone payment as revenue in its entirety upon our achievement of a substantive milestone if the consideration earned from the achievement of the milestone (i) is consistent with performance required to achieve the milestone or the increase in value to the delivered item, (ii) relates solely to past performance and (iii) is reasonable relative to all of the other deliverables and payments within the arrangement. We 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, LLC and its subsidiaries. See Note 7.

d. Recent Accounting Pronouncements: In February 2015, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2015-02, Amendments to the Consolidation Analysis. ASU 2015-02 affects reporting entities that are required to evaluate whether they should consolidate certain legal entities. All legal entities are subject to reevaluation under the revised consolidation model. Specifically, the amendments: (i) modify the evaluation of whether limited partnerships and similar legal entities are variable interest entities (VIEs) or voting interest entities, (ii) eliminate the presumption that a general partner should consolidate a limited partnership, and (iii) affect the consolidation analysis of reporting entities that are involved with VIEs, particularly those that have fee arrangements and related party relationships. ASU 2015-02 is effective for public entities for fiscal years, and for interim periods within those fiscal years, beginning after December 15, 2015. The amendments may be applied using a modified retrospective approach or a full retrospective approach. Early adoption is permitted, including

adoption in an interim period. We are currently evaluating the impact of our adoption of ASU 2015-02, however we do not expect the adoption of ASU 2015-02 to have a material effect on our consolidated financial statements upon adoption.

In April 2015, the FASB issued ASU No. 2015-03, Simplifying the Presentation of Debt Issuance Costs. ASU 2015-003 requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability rather than as an asset. The recognition and measurement guidance for debt issuance costs are not affected by ASU 2015-03. ASU 2015-03 is effective for fiscal years beginning after December 15, 2015, and interim periods within those fiscal years. Early adoption is permitted. Entities must apply the amendments in ASU 2015-03 on a retrospective basis. We do not expect the adoption of ASU 2015-03 to have a material effect on our consolidated financial statements upon adoption.

2. Fair Value

Platinum-Montaur Life Sciences, LLC (Platinum) has the right to convert all or any portion of the unpaid principal or unpaid interest accrued on any draws subsequent to the second quarter of 2013 under the Platinum credit facility, under certain circumstances. Platinum's option to convert such subsequent draws into common stock was determined to meet the definition of a liability and is included as part of the value of the related notes payable on the consolidated balance sheets. The estimated fair value of the Platinum notes payable is \$6.9 million at March 31, 2015, and will continue to be measured on a recurring basis. See Note 8.

MT issued warrants to purchase 300 shares of MT Common Stock in connection with the sale of 10 shares of MT Preferred Stock in March 2015. In accordance with current accounting guidance, the warrants are required to be accounted for as a derivative liability at fair value, with subsequent changes in fair value included in earnings. The estimated fair value of the MT warrants is \$63,000 at March 31, 2015, and will continue to be measured on a recurring basis. See Notes 6 and 9.

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, 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	\$—	\$—	\$6,888,661	\$6,888,661
Liability related to warrants	—	—	63,000	63,000

Liabilities Measured at Fair Value on a Recurring Basis as of December 31, 2014

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	\$—	\$—	\$5,615,764	\$5,615,764

Valuation Processes-Level 3 Measurements: Depending on the instrument, the Company utilizes discounted cash flows, option pricing models, or third-party valuation services to estimate the value of their financial assets and liabilities. Valuations using discounted cash flow methods and certain option pricing models such as Black-Scholes are generally conducted by the Company or by third-party valuation experts. Valuations using complex models such as a Monte Carlo simulation are generally provided to the Company by third-party valuation experts. Each reporting period, the Company provides significant unobservable inputs to the third-party valuation experts based on current internal estimates and forecasts.

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, management's estimate of the likelihood of actually making those draws as opposed to obtaining other sources of financing, and management's estimate of the likelihood of those draws ultimately resulting in Platinum exercising their conversion option under the Platinum Loan Agreement. 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, 2015 and 2014. There were no transfers in or out of our Level 2 liabilities during the three-month periods ended March 31, 2015 or 2014. The change in the estimated fair value of our Level 3 liabilities relating to unrealized gains was \$1.7 million and \$394,000, respectively, which were recorded as changes in fair value of financial instruments during the three-month periods ended March 31, 2015 and 2014.

3. Stock-Based Compensation

At March 31, 2015, we have instruments outstanding under two stock-based compensation plans; the Fourth Amended and Restated 2002 Stock Incentive Plan (the 2002 Plan) and the Amended and Restated 2014 Stock Incentive Plan (the 2014 Plan). In addition, we have stock options outstanding that were awarded as an employment inducement in connection with the appointment of our new CEO in October 2014. Currently, under the 2014 Plan, we may grant incentive stock options, nonqualified stock options, and restricted stock awards to full-time employees and directors, and nonqualified stock options and restricted stock awards may be granted to our consultants and agents. Total shares authorized under each plan are 12 million shares and 5 million shares, respectively. Although instruments are still outstanding under the 2002 Plan, the plan has expired and no new grants may be made from it. Under both plans, the exercise price of each option is greater than or equal to the closing market price of our common stock on the date of the grant.

Stock options granted under the 2002 Plan and the 2014 Plan generally vest on an annual basis over one to four years. The stock options that were awarded as an employment inducement in connection with the appointment of our new CEO will vest in three tranches based on certain service and market conditions as defined in the agreement. Outstanding stock options under the plans, if not exercised, generally expire ten years from their date of grant or up to 90 days following the date of an optionee's separation from employment with the Company. We issue new shares of our common stock upon exercise of stock options.

Stock-based payments to employees and directors, including grants of stock options, are recognized in the consolidated statements of operations based on their estimated fair values. The fair value of each stock option award is estimated on the date of grant using the Black-Scholes option pricing model. Expected volatilities are based on the Company's historical volatility, which management believes represents the most accurate basis for estimating expected future volatility under the current circumstances. Navidea uses historical data to estimate forfeiture rates. The expected term of stock options granted is based on the vesting period and the contractual life of the options. The risk-free rate is based on the U.S. Treasury yield in effect at the time of the grant.

The portion of the fair value of stock-based awards that is ultimately expected to vest is recognized as compensation expense over either (1) the requisite service period or (2) the estimated performance period. Restricted stock awards are valued based on the closing stock price on the date of grant and amortized ratably over the estimated life of the award. Restricted stock may vest based on the passage of time, or upon occurrence of a specific event or achievement of goals as defined in the grant agreements. In such cases, we record compensation expense related to grants of restricted stock based on management's estimates of the probable dates of the vesting events. Stock-based awards that do not vest because the requisite service period is not met prior to termination result in reversal of previously recognized compensation cost.

For the three-month periods ended March 31, 2015 and 2014, our total stock-based compensation expense was approximately \$1.1 million and \$693,000, respectively. We have not recorded any income tax benefit related to stock-based compensation in either of the three-month periods ended March 31, 2015 and 2014.

A summary of the status of our stock options as of March 31, 2015, and changes during the three-month period then ended, is presented below:

Three Months Ended March 31, 2015			
Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value

Edgar Filing: NAVIDEA BIOPHARMACEUTICALS, INC. - Form 10-Q

Outstanding at beginning of period	5,345,764	\$2.16		
Granted	1,169,100	1.69		
Outstanding at end of period	6,514,864	\$2.07	7.7 years	\$877,344
Exercisable at end of period	2,880,199	\$2.31	5.9 years	\$534,643

11

A summary of the status of our unvested restricted stock as of March 31, 2015, and changes during the three-month period then ended, is presented below:

	Three Months Ended March 31, 2015	
	Number of Shares	Weighted Average Grant-Date Fair Value
Unvested at beginning of period	498,250	\$1.91
Granted	332,000	1.73
Vested	(140,000)) 2.28
Forfeited	(18,750)) 1.26
Unvested at end of period	671,500	\$1.76

In February 2015, 120,000 shares of restricted stock held by non-employee directors with an aggregate fair value of \$193,000 vested as scheduled according to the terms of the restricted stock agreements. In March 2015, 20,000 shares of restricted stock held by an employee with an aggregate fair value of \$33,000 vested as scheduled according to the terms of a restricted stock agreement.

As of March 31, 2015, there was approximately \$2.1 million of total unrecognized compensation expense related to unvested stock-based awards, which we expect to recognize over the remaining weighted average vesting term of 2.1 years.

4. 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, 2015 and 2014 excludes the effects of 20.1 million and 19.2 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, approximately 672,000 and 605,000 shares of unvested restricted stock were excluded in determining basic and diluted loss per share for the three-month periods ended March 31, 2015 and 2014, respectively, because such inclusion would be anti-dilutive.

5. 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.

The components of inventory as of March 31, 2015 and December 31, 2014, net of reserves of \$659,000 and \$539,000, respectively, are as follows:

	March 31, 2015 (unaudited)	December 31, 2014
Work-in-process	\$360,442	\$495,449
Finished goods	211,163	436,936
Total	\$571,605	\$932,385

During the three-month period ended March 31, 2015, we reserved an additional \$120,000 of materials related to production issues. During the three-month periods ended March 31, 2015 and 2014, we wrote off \$37,000 and \$10,000, respectively, of previously capitalized Lymphoseek inventory due to the consumption of the Lymphoseek material for product testing and development purposes.

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.

6. Investment in Macrophage Therapeutics, Inc.

In March 2015, MT, our previously wholly-owned subsidiary, entered into a Securities Purchase Agreement to sell up to 50 shares of its Series A Convertible Preferred Stock (MT Preferred Stock) and warrants to purchase up to 1,500 common shares of MT (MT Common Stock) to Platinum-Montaur Life Sciences, LLC (Platinum) and Dr. Michael Goldberg for a purchase price of \$50,000 per unit. A unit consists of one share of MT Preferred Stock and 30 warrants to purchase MT Common Stock. Under the agreement, 40% of the MT Preferred Stock and warrants are committed to be purchased by Dr. Goldberg, and the balance by Platinum. The full 50 shares of MT Preferred Stock and warrants to be sold under the agreement are convertible into, and exercisable for, MT Common Stock representing an aggregate 1% interest on a fully converted and exercised basis. Navidea owns the remainder of the MT Common Stock. On March 11, 2015, definitive agreements with the investors were signed for the sale of the first tranche of 10 shares of MT Preferred Stock and warrants to purchase 300 shares of MT Common Stock to these investors, with gross proceeds to MT of \$500,000. The MT Common Stock held by parties other than Navidea is reflected on the consolidated balance sheets as a noncontrolling interest.

In accordance with current accounting guidance, the warrants are required to be accounted for separately as a derivative liability at fair value, with subsequent changes in fair value to be included in earnings. The fair value of the warrants was estimated to be \$63,000 at issuance and at March 31, 2015. In addition, the conversion option within the MT Preferred Stock was determined to be a beneficial conversion feature. The conversion option was immediately convertible upon issuance, resulting in a deemed dividend of \$46,000 related to the beneficial conversion feature. Finally, certain provisions of the Securities Purchase Agreement obligate the investors to acquire the remaining MT Preferred Stock and related warrants for \$2.0 million at the option of MT. The estimated relative fair value of this put option was \$113,000 at issuance based on the Black-Scholes option pricing model and is classified within stockholders' equity.

In addition, we entered into a Securities Exchange Agreement with the investors providing them an option to exchange their MT Preferred Stock for our common stock in the event that MT has not completed a public offering with gross proceeds to MT of at least \$50 million by the second anniversary of the closing of the initial sale of MT Preferred Stock, at an exchange rate per share obtained by dividing \$50,000 by the greater of (i) 80% of the twenty-day volume weighted average price per share of our common stock on the second anniversary of the initial closing or (ii) \$3.00. To the extent that the investors do not timely exercise their exchange right, MT has the right to

redeem their MT Preferred Stock for a price equal to \$58,320 per share. We also granted MT an exclusive license for certain therapeutic applications of the Manocept technology.

7. Investment in R-NAV, LLC

Navidea's investment in R-NAV, LLC (R-NAV) of approximately 33% is being accounted for using the equity method of accounting. Navidea's equity in the loss of R-NAV was \$262,227 for the three-month period ended March 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 \$21,000 of in-kind services during the three-month period ended March 31, 2015. As of March 31, 2015, the Company has \$441,000 of in-kind services remaining to provide under this obligation.

8. Notes Payable

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. As of March 31, 2015, the outstanding principal balance of the Oxford Loan Notes was \$30 million, and we were in compliance with all covenants of the Oxford Loan Agreement.

In connection with the Oxford Loan Agreement, the Company recorded a debt discount related to the issuance of the Series KK Warrants and other fees to the lenders totaling \$3.0 million. Debt issuance costs directly attributable to the Oxford Loan Agreement, totaling \$120,000, were recorded as a non-current asset on the consolidated balance sheet on the closing date. The debt discount and debt offering costs are being amortized as non-cash interest expense using the effective interest method over the term of the Oxford Loan Agreement. As of March 31, 2015, the balance of the debt discount was \$2.2 million, and the balance of the debt issuance costs was \$81,000.

Our loan agreement with Platinum, as amended, provides us with a credit facility of up to \$50 million (the Second Amended Platinum Note). The Company borrowed an additional \$3.0 million under the Second Amended Platinum Note during the three months ended March 31, 2015. The Second Amended Platinum Note is reflected on the consolidated balance sheets at its estimated fair value, which includes the estimated fair value of an embedded conversion option. A net decrease in the estimated fair value of the Second Amended Platinum Note of \$1.7 million was recorded as a non-cash change in fair value of financial instruments during the three-month period ended March 31, 2015. The estimated fair value of the Second Amended Platinum Note was \$6.9 million as of March 31, 2015. As of March 31, 2015, the outstanding principal balance of the Second Amended Platinum Note was approximately \$6.2 million, with \$28.8 million still available under the credit facility.

As of March 31, 2015, the outstanding principal balance of the Note Payable to R-NAV was \$666,666.

During the three-month periods ended March 31, 2015 and 2014, we recorded interest expense of \$967,000 and \$944,000, respectively, related to our notes payable. Of these amounts, \$213,000 and \$242,000, respectively, related to amortization of the debt discounts and deferred financing costs related to our notes payable.

9. Derivative Instruments

Certain embedded features of our convertible securities, notes payable, or warrants to purchase our common stock, may be treated as derivative liabilities. The estimated fair values of the derivative liabilities are recorded as non-current liabilities on the consolidated balance sheet. Changes in the estimated fair values of the derivative liabilities are recorded in the consolidated statement of operations as non-cash income (expense). We do not use derivative instruments for hedging of market risks or for trading or speculative purposes.

At March 31, 2015, derivative liabilities consist of warrants to purchase MT Common Stock, issued to Platinum and Dr. Michael Goldberg. Derivative liabilities outstanding during the three-month period ended March 31, 2014 consisted of a Series JJ warrant issued to Crede CG III, Ltd. related to a 2013 registered direct public offering. The Series JJ warrant was exchanged for common stock during the fourth quarter of 2014. The net effect of marking the Company's derivative liabilities to market during the three-month period ended March 31, 2014 resulted in changes in the estimated fair value of the derivative liabilities relating to unrealized losses of approximately \$1,000 which were

recorded as changes in the fair value of financial instruments. The total estimated fair value of our derivative liabilities was \$63,000 as of March 31, 2015. See Note 1b(3).

10. Equity

During the three-month period ended March 31, 2015, we issued 36,839 shares of our common stock valued at \$70,000 to certain members of our Board of Directors as payment in lieu of cash for a portion of their fourth quarter 2014 compensation.

As of March 31, 2015, there are 4,519 shares of Series B Preferred Stock outstanding which are convertible into 14,777,130 shares of our common stock.

11. Stock Warrants

At March 31, 2015, there are 1.8 million warrants outstanding to purchase Navidea's common stock. The warrants are exercisable at prices ranging from \$1.918 to \$3.04 per share with a weighted average exercise price of \$2.27 per share.

In addition, at March 31, 2015, there are 300 warrants outstanding to purchase MT Common Stock. The warrants are exercisable at \$2,000 per share.

12. Reduction in Force

In March 2015, the Company initiated a reduction in force that will include seven staff members and four executives. Three of the executives will continue as employees during transition periods of varying lengths, depending upon the nature and extent of responsibilities to be transitioned or wound down. As of March 31, 2015, the specific terms of the transition and separation of two of the executives were still being determined.

During the three-month period ended March 31, 2015, the Company recognized approximately \$1.4 million of net expense as a result of the reduction in force, which includes actual and estimated separation costs as well as the impact of accelerated vesting or forfeiture of certain equity awards resulting from the separation of \$372,000.

A summary of changes in accrued separation costs during the three-month period ended March 31, 2015 is presented below:

Accrued separation costs, beginning of period	\$449,351	
Payments related to May 2014 reduction in force	(405,187)
Charges incurred with March 2015 reduction in force	1,039,598	
Payments related to March 2015 reduction in force	(28,630)
Accrued separation costs, end of period	\$1,055,132	

The following table summarizes the remaining accrued separation costs, including estimated employer payroll tax obligations, related to the Company's reduction in force, which are included in accrued liabilities and other on the consolidated balance sheet as of March 31, 2015:

	As of
	March 31, 2015
Separation payments, including payroll taxes	\$964,013
Estimated cost of continuing healthcare coverage	91,119
	\$1,055,132

13. Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases, and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. Due to the uncertainty surrounding the realization of the deferred tax assets in future tax returns, all of the deferred tax assets have been fully offset by a valuation allowance at March 31, 2015 and December 31, 2014.

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

15

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, 2015 or December 31, 2014 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, 2015, tax years 2011-2014 remained subject to examination by federal and state tax authorities.

14. Segments

We report information about our operating segments using the “management approach” in accordance with current accounting standards. This information is based on the way management organizes and reports the segments within the enterprise for making operating decisions and assessing performance. Our reportable segments are identified based on differences in products, services and markets served. There were no inter-segment sales. Prior to 2015, our products and development programs were all related to diagnostic substances. Our majority-owned subsidiary, Macrophage Therapeutics, Inc., was formed and received initial funding during the first quarter of 2015, which resulted in a re-evaluation of the Company's segment determination. We now manage our business based on two primary types of drug products: (i) diagnostic substances, including Lymphoseek and our Manocept platform, our R-NAV subsidiary, NAV4694 and NAV5001, and (ii) therapeutic development programs, including all development programs undertaken by Macrophage Therapeutics, Inc.

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

(\$ amounts in thousands)	Diagnostics	Therapeutics	Corporate	Total
Three Months Ended March 31, 2015				
Lymphoseek sales revenue:				
United States ¹	\$1,831	\$—	\$—	\$1,831
International	6	—	—	6
Lymphoseek license revenue	83	—	—	83
Grant and other revenue	190	—	—	190
Total revenue	2,108	—	—	2,108
Research and development expenses	3,895	86	—	3,981
Selling, general and administrative expenses, excluding depreciation and amortization ²	2,042	14	3,324	5,380
Depreciation and amortization	72	—	78	150
Loss from operations ³	(4,315)	(100)	(3,401)	(7,816)
Other income (expense), excluding equity in the loss of R-NAV, LLC ⁴	—	—	787	787
Equity in the loss of R-NAV, LLC	—	—	(262)	(262)
Loss attributable to common stockholders	(4,315)	(146)	(2,876)	(7,337)
Total assets, net of depreciation and amortization:				
United States	3,334	7	7,078	10,419
International	496	—	3	499
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 Loss from operations does not reflect the allocation of certain selling, general and administrative expenses, excluding depreciation and amortization, to our individual reportable segments.

⁴ Amounts consist primarily of interest income, interest expense and changes in fair value of financial instruments, which are not currently allocated to our individual reportable segments.

15. Supplemental Disclosure for Statements of Cash Flows

During the three-month periods ended March 31, 2015 and 2014, we paid interest aggregating \$701,000 and \$907,000, respectively. During the three-month period ended March 31, 2015, we issued 68,157 shares of our common stock as employer matching contributions to our 401(k) plan valued at \$117,000.

In connection with their initial investment in March 2015, the investors in MT were issued warrants that have been determined to be derivative liabilities with an estimated fair value of \$63,000. A \$46,000 deemed dividend related to the beneficial conversion feature within the MT Preferred Stock was also recorded at the time of the initial investment in MT.

16. Subsequent Events

Debt Refinancing: In May 2015, we executed a Loan Agreement (the CRG Loan Agreement) with Capital Royalty Group (CRG) providing for an initial funding of \$50 million and bearing interest at 14.0% (the CRG Note). The initial funding is expected to be received by the end of May 2015. We will make quarterly payments of interest only beginning three months after initial funding. Commencing four years after initial funding, the Company will make 24 consecutive equal monthly payments of principal and interest. All unpaid principal, and accrued and unpaid interest, along with an end-of-term final payment fee of \$2.5 million, will be due and payable in full six years after the closing date. The CRG Note will be collateralized by a security interest in substantially all of the Company's assets. The CRG Loan Agreement requires that the Company adhere to certain affirmative and negative covenants, including, without limitation, 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 majority of the proceeds from the CRG Note will be used to repay all amounts outstanding under the Oxford Loan Agreement of approximately \$31.6 million, including payments of \$300,000 as a pre-payment fee and \$2.4 million as an end-of-term final payment fee. The remaining proceeds will be used to support the growth of the Company's Manocept technology and for general operating purposes.

Platinum Credit Facility: The Company drew a total of \$1.5 million under the Platinum credit facility in April 2015. In May 2015, in connection with the execution of the CRG Loan Agreement, the Company also amended the existing Platinum credit facility to allow this facility to remain in place in a subordinated role to the CRG Loan. The amendment will become effective upon initial funding of the CRG Loan Agreement and will allow Platinum to convert the entire \$7.7 million currently outstanding under the credit facility during a time period in which the Company's stock price exceeds \$2.53 per share for 10 consecutive trading days.

Sublicense Termination Agreement: In April 2015, the Company entered into an agreement with Alseres Pharmaceuticals, Inc. (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 will transfer all regulatory, clinical and manufacturing-related data related to NAV5001 to Alseres. Alseres will reimburse Navidea for any incurred maintenance costs of the contract manufacturer retroactive to March 1, 2015. In addition, as requested by Alseres, Navidea will supply clinical support services for NAV5001 on a cost-plus reimbursement basis. In consideration for the rights granted to Alseres, Navidea will also receive a milestone payment upon clearance to market NAV5001 by the U.S. FDA and a royalty on subsequent net sales of NAV5001.

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 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., a Delaware corporation, is a precision medicine company focused on the development and commercialization of precision diagnostic and therapeutic agents. Navidea is developing multiple precision-targeted products based on the 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 of the chemical backbone of the tilmanocept molecule to specifically target the CD206 mannose receptor expressed on over-activated macrophages. The Manocept platform serves as the molecular backbone of Lymphoseek® (technetium Tc 99m tilmanocept) injection, the first product developed 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 being developed by the Company using tilmanocept linked to various therapeutic agents 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. Thus, in January 2015, the Company formed a new subsidiary, Macrophage Therapeutics, Inc., to further explore therapeutic applications for the Manocept platform.

In addition, over the last year, the company's Board of Directors made the decision to reduce our support while seeking to partner or out-license two of our development programs:

- NAV4694 is a fluorine-18 (F-18) radiolabeled PET imaging agent being developed as an aid in the diagnosis of patients with signs or symptoms of Alzheimer's disease (AD) and mild cognitive impairment (MCI). NAV4694 is in Phase 3 clinical development. The Company is currently engaged in evaluating term sheets related to NAV4694.

- NAV5001 is an iodine-123 (I-123) radiolabeled 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. NAV5001 is in Phase 3 clinical development. In April 2015, the Company entered into an agreement with Alseres Pharmaceuticals, Inc. (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 will transfer all regulatory, clinical

and manufacturing-related data related to NAV5001 to Alseres. Alseres will reimburse Navidea for any incurred maintenance costs of the contract manufacturer retroactive to March 1, 2015. In addition, as requested by Alseres, Navidea will supply clinical support services for NAV5001 on a cost-plus reimbursement basis. In consideration for the rights granted to Alseres, Navidea will also receive a milestone payment upon clearance to market NAV5001 by the U.S. FDA and a royalty on subsequent net sales of 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 more recently on our other pipeline programs, including NAV4694, NAV5001, and our Manocept platform. 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 has primarily involved reducing our near-term support for our two neurological product candidates, NAV4694 and NAV5001, as we seek to secure a development partner or partners for these programs.

Navidea remains committed to realizing the full potential of Lymphoseek. We intend to deploy our own sales team and strategy to accelerate the strong growth of this important product. The Company believes that the resources being devoted to drive Lymphoseek sales will lead to positive cash flows and profitability. The Company is focused on expanding the market for Lymphoseek in all relevant markets.

The Company is also 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 venture which began in July 2014, and the formation of Macrophage Therapeutics, Inc. in January 2015, which we believe may further expand the Company's pipeline but which require less near-term funding from Navidea than the two ongoing Phase 3 neurological development programs.

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 PDUFA 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 an ongoing trial in colorectal cancer, and

others in various stages of execution, planning or consideration, are anticipated to provide additional data to potentially support 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.

Lymphoseek - Clinical Data Background

In January 2015, we announced that an analysis comparing sentinel lymph node (SLN) biopsy procedures using Lymphoseek (TcTM) + vital blue dye (VDB) to filtered [99mTc] sulfur colloid (fTcSC) + VDB in breast cancer patients was published in the *Annals of Surgical Oncology*. Results demonstrated that (i) Lymphoseek patients had significantly fewer SLNs removed per procedure (mean TcTM: 1.85 vs. fTcSC: 3.24, $p < 0.0001$); (ii) proportionally fewer nodes were necessary to detect cancer spread; and (iii) nodes removed using Lymphoseek held greater predictive value for diagnosing the spread of breast cancer to lymph nodes. The study, "Comparison of [99mTc]Tilmanocept and Filtered [99mTc]Sulfur Colloid for Identification of SLNs in Breast Cancer Patients," authored by Anne Wallace, M.D., et. al., at the UC San Diego School of Medicine was published in the January print issue of the journal *Annals of Surgical Oncology*.

In February 2015, we announced the peer-reviewed publication of results from a Phase 3 clinical trial of Lymphoseek in patients with certain head and neck cancer in the journal *Annals of Surgical Oncology*. The trial assessed the performance of Lymphoseek-guided sentinel node biopsy against the standard of care, nodal pathology, in planned elective neck dissection. Results demonstrated that Lymphoseek met the primary efficacy endpoint of accurately identifying sentinel lymph nodes in subjects with node-negative squamous cell carcinoma of the oral cavity, as compared to the removal of all lymph nodes during multiple level nodal dissection surgery of the head and neck. Pathology assessment of lymph nodes from the multiple-level nodal dissection surgery is considered the "gold standard" to determine the presence and extent of cancer spread. The study, "[99mTc]Tilmanocept Accurately Detects Sentinel Lymph Nodes and Predicts Pathology Status in Patients with Oral Squamous Cell Carcinoma of the Head and Neck: Results of a Phase III Multi-Institutional Trial" was published as an Online First article in the journal *Annals of Surgical Oncology*. Data from this study were previously presented in part at the 2013 Society of Nuclear Medicine and Molecular Imaging Annual Meeting (Vancouver, British Columbia), at the 2013 American College of Surgeons Clinical Congress (Washington, DC), and at the 6th European Congress on Head and Neck Oncology-2014 (Liverpool, UK).

An investigator-initiated study is currently underway at the University of California, San Diego (UCSD) to evaluate injection site pain between Lymphoseek and an alternative radiopharmaceutical that is commonly used in lymphatic mapping procedures. The study is designed to determine if patients receiving Lymphoseek experience the same or less pain following injection compared to radiolabeled sulfur colloid, and to measure the amount of discomfort that patients report during and after injection, as well as other characteristics of performance.

Manocept Platform - Diagnostics and Therapeutics Background

Navidea's Manocept platform is predicated on the ability to specifically target the CD206 mannose receptor expressed on over-activated macrophages. Over-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 enhance diagnostic accuracy, clinical decision-making and ultimately patient care, while offering the potential to utilize a breadth of diagnostic modalities, including SPECT, PET, intra-operative and/or optical-fluorescence detection, as well as the potential delivery of therapeutic compounds targeting 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 these 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, tuberculosis (TB), systemic lupus erythematosus, Kaposi's Sarcoma (KS), and others that span clinical areas in oncology, autoimmunity, infectious diseases, cardiology, and inflammation. Data from studies using agents from the Manocept platform in RA, KS and 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.

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 program, or radio-immuno-guided surgery. RIGS was originally intended to use a monoclonal antibody as an aid in identifying 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, prostate cancer, lung cancer and other cancers of epithelial origin. The detection of clinically occult tumor is intended to provide the surgeon with a more accurate assessment of the extent and location of disease, and therefore may impact the surgical and therapeutic management of the patient.

Our most recent comments regarding our RIGS[®] (radioimmunguided surgery) program had indicated the lower prioritization of this program relative to our other development activities and comments to the effect that we would not be spending on this program beyond the boundaries of the \$1.5 million grant we were awarded in September 2012. Part of our ongoing consideration of the RIGS program has involved an evaluation of the manufacturability of the monoclonal antibody known as CC49 and its humanized derivative, and ultimately their clinical and commercial viability. In recent years, these evaluations have caused us to question the viability of the monoclonal antibody initiative as it was originally envisioned. During the same time period, we've learned more about tilmanocept, the underlying Manocept backbone, and the potential utility of tilmanocept in identifying tumor-associated macrophages (TAMs), and their consequent potential utility in identifying tumor itself. To that end, we petitioned the NIH to repurpose the grant we were previously awarded towards the study of TAMs in colorectal cancer. We recently received confirmation of the acceptance of this repurposing. We expect this repurposed grant will now support the collaboration we entered into in November 2013 with investigators at the University of Alabama at Birmingham (UAB) to assess diagnostic approaches in colorectal cancer patients. We recognize this repurposing represents a major refocusing of the original RIGS 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're 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 December 2014, the Company formed a new business unit, Macrophage Therapeutics, to further explore therapeutic applications for the Manocept platform. In January 2015, we incorporated the business unit as Macrophage Therapeutics, Inc. (MT), initially a wholly-owned subsidiary of Navidea.

Also in December 2014, MT hosted a conference where data was presented using the Manocept platform compound, tilmanocept, that was generated by independent academic collaborators with expertise in the HIV/AIDS, cancer, TB, RA and cardiovascular disease therapeutic areas. The technical presentations highlighted tilmanocept's ability to target activated macrophages implicated in pathology.

In February 2015, we announced the appointment of leading experts to a newly formed scientific advisory board (SAB) to serve as a strategic resource to MT as it 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 management with counsel and guidance pertaining to the research, development, and clinical use of our Manocept technology in therapeutic applications.

In March 2015, MT entered into a Securities Purchase Agreement to sell up to 50 shares of its Series A Convertible Preferred Stock (MT Preferred Stock) and warrants to purchase up to 1,500 common shares of Macrophage Therapeutics, Inc. (MT Common Stock) to Platinum-Montaur Life Sciences, LLC (Platinum) and Dr. Michael Goldberg for a purchase price of \$50,000 per unit. On March 13, 2015, we announced that definitive agreements with the investors had been signed for the sale of the first tranche of 10 shares of MT Preferred Stock and warrants to purchase 300 shares of MT Common Stock to these investors, with gross proceeds to MT of \$500,000. Under the agreement, 40% of the MT Preferred Stock and warrants are committed to be purchased by Dr. Goldberg, and the balance by Platinum. The full 50 shares of MT Preferred Stock and warrants to be sold under the agreement are convertible into and exercisable for MT Common Stock representing an aggregate 1% interest on a fully converted and exercised basis. The Company owns the remainder of the MT Common Stock.

In addition, we entered into a Securities Exchange Agreement with the investors providing them an option to exchange their MT Preferred Stock for our common stock in the event that MT has not completed a public offering with gross proceeds to MT of at least \$50 million by the second anniversary of the closing of the initial sale of MT Preferred Stock, at an exchange rate per share obtained by dividing \$50,000 by the greater of (i) 80% of the twenty-day volume weighted average price per share of our common stock on the second anniversary of the initial closing or (ii) \$3.00. To the extent that the investors do not timely exercise their exchange right, MT has the right to redeem their MT Preferred Stock for a price equal to \$58,320 per share. We also granted MT an exclusive license for certain therapeutic applications of the Manocept technology.

In March 2015, MT announced that data from an ongoing human study indicates that the Manocept technology platform has the ability to safely cross the blood brain barrier without losing its ability to deliver its payload to the intended target. Based on this data and on the advice of the Company's SAB, MT will expand the SAB to include members with specific expertise in central nervous system (CNS) disease. 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, lesions on the other side of the blood brain barrier were observed. 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 April 2015, MT reported data at the American Association of Cancer Research Annual Meeting demonstrating that the Manocept molecule selectively binds to, and is continuously internalized by, TAMs and KS tumor cells in a preclinical model. Preliminary results from a clinical study also demonstrated that a single, subcutaneous injection of Lymphoseek detects and localizes in KS tumors and the lymph nodes involved in draining the KS tumor fields. Collectively, the data demonstrate the potential for Manocept-based molecules to be used therapeutically to treat Kaposi's sarcoma. Modulation, including killing or modification of macrophage and KS expression profiles, represents a potential for a paradigm-shifting immunotherapeutic strategy.

The Company continues to evaluate emerging data in other disease states to define areas of focus, development pathways and partnering options to capitalize on the Manocept platform, including ongoing studies in KS and RA. The immune-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 Out-License)

NAV4694 is a Fluorine-18 labeled precision radiopharmaceutical candidate for use in the imaging and evaluation of patients with signs or symptoms of AD and potentially also 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 evaluating term sheets related to NAV4694.

NAV5001

NAV5001 is a patented Iodine-123 labeled small molecule radiopharmaceutical used with SPECT imaging to identify the status of specific regions in the brains of patients suspected of having PD. 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 will transfer all regulatory, clinical and manufacturing-related data related to NAV5001 to Alseres. Alseres will reimburse Navidea for any incurred maintenance costs of the contract manufacturer retroactive to March 1, 2015. In addition, as requested by Alseres, Navidea will supply clinical support services for NAV5001 on a cost-plus reimbursement basis. In consideration for the rights granted to Alseres, Navidea will also receive a milestone payment upon clearance to market NAV5001 by the U.S. FDA and a royalty on subsequent net sales of NAV5001.

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. We have begun the process of launching 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 most recently 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 \$4.0 million and \$5.2 million in total on research and development activities during the three-month periods ended March 31, 2015 and 2014, respectively. Of the total amounts we spent on research and development during those periods, excluding costs related to our internal research and development headcount and our general and administrative staff which we do not currently allocate among the various development programs that we have underway, we incurred out-of-pocket charges by program as follows:

Development Program	Three Months Ended March 31,	
	2015	2014
Lymphoseek	\$639,796	\$625,583
Manocept Platform	164,671	167,013
Macrophage Therapeutics	28,027	—
NAV4694	1,206,333	1,618,128
NAV5001	139,677	519,158
NAV1800	—	27,865

We expect to continue the advancement of our efforts with Lymphoseek and our Manocept platform during the remainder of 2015, however, we expect the cost of these advances to be more than offset by reductions in development costs of NAV4694 and NAV5001, and as a result, we expect our total research and development expenses for the remainder of 2015 to decrease significantly from 2014.

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. 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.

In March 2015, the Company initiated a reduction in force that will include seven staff members and four executives. Three of the executives will continue as employees during transition periods of varying lengths, depending upon the nature and extent of responsibilities to be transitioned or wound down. As of the filing date of this document, the specific terms of the executive transition and separation were still being determined. During the three-month period ended March 31, 2015, the Company recognized approximately \$1.4 million of net expense as a result of the reduction in force, which includes actual and estimated separation costs as well as the impact of accelerated vesting and the forfeiture of certain equity awards resulting from the separation. We anticipate that the initial cost of the reduction in force will be offset with savings on compensation expense in the longer term.

The Company reiterates its 2015 Lymphoseek product revenue estimate of \$10 million to \$12 million. Additionally, margins on Lymphoseek product sales are expected to approach and possibly exceed 80% in the coming quarters. The Company also expects, following completion of the partnering activities for NAV4694, that cash operating expenses on a quarterly basis will continue to decrease to the point necessary for the Company to achieve its goals of cash flow break-even from operations. This guidance excludes therapeutic-related research and development costs for the Manocept platform which are expected to be funded separately by Macrophage Therapeutics, Inc.

Results of Operations

Three Months Ended March 31, 2015 and 2014

Lymphoseek Sales and Margins. Net sales of Lymphoseek were \$1.8 million during the first quarter of 2015, compared to \$627,000 during the same period of 2014. The increase was primarily the result of continued efforts to increase sales following the initial product launch in late April of 2013. Gross margins on net sales were 76% and 69% for the first quarters of 2015 and 2014, respectively. Cost of goods sold in the first quarter of 2015 included net inventory losses of \$80,000 related to a production matter. 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 UCSD.

Lymphoseek License Revenue. During the first quarter of 2015, we recognized \$83,000 of the \$2.0 million non-refundable upfront payment received by the Company related to the recent Lymphoseek license and distribution agreement for Europe, which the Company is recognizing on a straight-line basis over two years. No Lymphoseek license revenue was recognized during the first quarter of 2014.

Grant and Other Revenue. During the first quarter of 2015, we recognized \$139,000 of grant revenue as compared to \$125,000 in the first quarter of 2014, primarily related to Small Business Innovation Research grants from the National Institutes of Health supporting NAV4694, Lymphoseek and Manocept platform development. The net increase was primarily due to higher NAV4694 and Lymphoseek grants offset by lower Manocept platform grants. Grant and other revenue for the first quarter of 2015 also included \$51,000 of revenue related to services provided to R-NAV for Manocept development.

Research and Development Expenses. Research and development expenses decreased \$1.2 million, or 24%, to \$4.0 million during the first quarter of 2015 from \$5.2 million during the same period in 2014. The decrease was primarily due to net decreases in drug project expenses related to (i) decreased NAV4694 development costs of \$412,000 including decreased manufacturing-related activities and regulatory costs, offset by increased clinical trial costs; and (ii) decreased NAV5001 development costs of \$379,000 including decreased clinical trial costs and decreased

manufacturing-related activities. The net decrease in research and development expenses also included decreased travel, office and other support costs of \$331,000 coupled with decreased compensation including incentive-based awards and other expenses related to net decreased headcount of \$135,000 following the first quarter 2015 and second quarter 2014 reductions in force.

Selling, General and Administrative Expenses. Selling, general and administrative expenses increased \$1.6 million, or 40%, to \$5.5 million during the first quarter of 2015 from \$3.9 million during the same period in 2014. The net increase was primarily due to increased compensation including incentive-based awards and other expenses related to the first quarter 2015 reduction in force coupled with increased commercial and medical headcount. The net increase in selling, general and administrative expenses also included a milestone fee due to UCSD related to the license agreement with SpePharm AG, increased investor relations costs, and increased out-of-pocket marketing expenses related to NAV4694.

Other Income (Expense). Other income, net, was \$525,000 during the first quarter of 2015 as compared to other expense, net of \$3.2 million during the same period in 2014. Interest expense increased \$23,000 to \$967,000 during the first quarter of 2015 from \$944,000 for the same period in 2014, primarily due to the higher interest related to the Oxford Note in 2015 versus the GECC/MidCap Notes in 2014, coupled with higher outstanding balances of the Platinum Note in 2015 compared to 2014. Of this interest expense, \$213,000 and \$242,000 in the first quarter of 2015 and 2014, respectively, was non-cash in nature related to the amortization of debt issuance costs and debt discounts related to the Oxford and GECC/MidCap Notes. For the first quarters of 2015 and 2014, we recorded non-cash income of \$1.7 million and \$392,000, respectively, related to changes in the estimated fair value of financial instruments. During the first quarter of 2014, we recorded a \$2.6 million loss on the extinguishment of the GECC/MidCap Notes. During the first quarter of 2015, we recorded non-cash expense from our equity in the loss of R-NAV of \$262,000.

Liquidity and Capital Resources

Cash balances decreased to \$4.9 million at March 31, 2015 from \$5.5 million at December 31, 2014. The net decrease was primarily due to cash used to fund our operations, mainly for research and development activities, of \$4.1 million, offset by draws under the Platinum credit facility of \$3.0 million and the issuance of MT Preferred Stock of \$500,000.

Operating Activities. Cash used in operations decreased \$5.1 million to \$4.1 million during the first quarter of 2015 compared to \$9.2 million used during the same period in 2014.

Accounts receivable increased to \$1.2 million at March 31, 2015 from \$817,000 at December 31, 2014, primarily due to increased receivables due from Cardinal Health resulting from the increase in sales of Lymphoseek.

Inventory levels decreased to \$572,000 at March 31, 2015 from \$932,000 at December 31, 2014, primarily due to finished goods inventory sold and materials inventory consumed for process development purposes coupled with a reserve for inventory losses related to materials for a specific lot which was unsuccessful due to equipment failure during the production process. We expect inventory levels to increase over the remainder of 2015 as we produce additional Lymphoseek inventory to meet increasing demand.

Accounts payable increased to \$1.9 million at March 31, 2015 from \$1.5 million at December 31, 2014, primarily due to net increased payables due to NAV4694, professional services, and Lymphoseek development vendors, offset by net decreased payables due to regulatory and Lymphoseek marketing vendors. Accrued liabilities and other current liabilities increased to \$3.9 million at March 31, 2015 from \$3.2 million at December 31, 2014, primarily due to increased accruals for the first quarter 2015 reduction in force, NAV4694 development costs, and a milestone payment due to UCSD resulting from the license agreement with SpePharm AG, offset by decreased accruals for medical education costs and Lymphoseek development costs. Our payable and accrual balances will continue to fluctuate but will likely decrease overall as we decrease our level of development activity related to NAV4694 and NAV5001, offset by planned increases in commercial activity related to Lymphoseek and development activity related to the Manocept platform.

Investing Activities. Investing activities provided \$15,000 during the first quarter of 2015 compared to using \$993,000 during the same period in 2014. Proceeds from sales of equipment of \$20,000 were offset by patent and trademark costs of \$6,000 during the first quarter of 2015. Capital expenditures of \$986,000 during the first quarter of 2014 were primarily for leasehold improvements, office furniture and NAV4694 production equipment. We expect our overall capital expenditures for the remainder of 2015 will be lower than for the same period in 2014.

Financing Activities. Financing activities provided \$3.5 million during the first quarter of 2015 compared to \$3.2 million provided during the same period in 2014. 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. The \$3.2 million provided by financing activities in the first quarter of 2014 consisted primarily of proceeds from the Oxford Notes of \$30.0 million, offset by payment of the principal and fees related to the extinguishment of the GECC/MidCap Notes as well as issuance costs related to the Oxford Notes of \$26.7 million.

Investment in Macrophage Therapeutics, Inc.

In March 2015, MT entered into a Securities Purchase Agreement to sell up to 50 shares of its Series A Convertible Preferred Stock (MT Preferred Stock) and warrants to purchase up to 1,500 common shares of Macrophage Therapeutics, Inc. (MT Common Stock) to Platinum-Montaur Life Sciences, LLC (Platinum) and Dr. Michael Goldberg for a purchase price of \$50,000 per unit. Under the agreement, 40% of the MT Preferred Stock and warrants are committed to be purchased by Dr. Goldberg, and the balance by Platinum. The full 50 shares of MT Preferred Stock and warrants to be sold under the agreement

are convertible into and exercisable for MT Common Stock representing an aggregate 1% interest on a fully converted and exercised basis. The Company owns the remainder of the MT Common Stock. On March 11, 2015, definitive agreements with the investors were signed for the sale of the first tranche of 10 shares of MT Preferred Stock and warrants to purchase 300 shares of MT Common Stock to these investors, with gross proceeds to MT of \$500,000.

In addition, we entered into a Securities Exchange Agreement with the investors providing them an option to exchange their MT Preferred Stock for our common stock in the event that MT has not completed a public offering with gross proceeds to MT of at least \$50 million by the second anniversary of the closing of the initial sale of MT Preferred Stock, at an exchange rate per share obtained by dividing \$50,000 by the greater of (i) 80% of the twenty-day volume weighted average price per share of our common stock on the second anniversary of the initial closing or (ii) \$3.00. To the extent that the investors do not timely exercise their exchange right, we have the right to redeem their MT Preferred Stock for a price equal to \$58,320 per share. We also granted MT an exclusive license for certain therapeutic applications of the Manocept technology.

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 \$262,000 for the three-month period ended March 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 \$21,000 of in-kind services during the three-month period ended March 31, 2015. As of March 31, 2015, the Company has \$441,000 of in-kind services remaining to provide under this obligation. As of March 31, 2015, the outstanding principal balance of the Note Payable to R-NAV was \$666,666.

Capital Royalty Group Debt

In May 2015, we executed a Loan Agreement (the CRG Loan Agreement) with Capital Royalty Group (CRG) providing for an initial funding of \$50 million and bearing interest at 14.0% (the CRG Note). The initial funding is expected to be received by the end of May 2015. We will make quarterly payments of interest only beginning three months after initial funding. Commencing four years after initial funding, the Company will make 24 consecutive equal monthly payments of principal and interest. All unpaid principal, and accrued and unpaid interest, along with an end-of-term final payment fee of \$2.5 million, will be due and payable in full six years after the closing date. The CRG Note will be collateralized by a security interest in substantially all of the Company's assets. The CRG Loan Agreement requires that the Company adhere to certain affirmative and negative covenants, including, without limitation, 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 majority of the proceeds from the CRG Note will be used to repay all amounts outstanding under the Oxford Loan Agreement. The remaining proceeds will be used to support the growth of the Company's Manocept technology and for general operating purposes.

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 \$30,000,000, 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. As of March 31, 2015, the outstanding principal balance of the Oxford Loan Notes was \$30 million, and we were in compliance with all covenants of the Oxford Loan Agreement.

We will use the majority of the proceeds from the CRG Note to repay all amounts outstanding under the Oxford Loan Agreement totaling approximately \$31.6 million, including payments of \$300,000 as a pre-payment fee and \$2.4 million million as an end-of-term final payment fee.

Platinum Credit Facility

Our loan agreement with Platinum, as amended, provides us with a credit facility of up to \$50 million (the Second Amended Platinum Note). The Company borrowed an additional \$3.0 million under the Second Amended Platinum Note during the three months ended March 31, 2015. As of March 31, 2015, the outstanding principal balance of the Second Amended Platinum Note was approximately \$6.2 million, with \$28.8 million still available under the credit facility.

The Company drew a total of \$1.5 million under the Platinum credit facility in April 2015. In May 2015, in connection with the execution of the CRG Loan Agreement, the Company also amended the existing Platinum credit facility to allow this facility to remain in place in a subordinated role to the CRG Loan. The amendment will become effective upon initial funding of the CRG Loan Agreement and will allow Platinum to convert the entire \$7.7 million currently outstanding under the credit facility during a time period in which the Company's stock price exceeds \$2.53 per share for 10 consecutive trading days. Following the April 2015 draw and the May 2015 amendment, \$27.3 million will still be available under the credit facility.

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 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.

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 two neurological product candidates, NAV4694 and NAV5001, as we sought to secure a development partner or partners for these programs. 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 will transfer all regulatory, clinical and manufacturing-related data related to NAV5001 to Alseres. Alseres will reimburse Navidea for any incurred maintenance costs of the contract manufacturer retroactive to March 1, 2015. In addition, as requested by Alseres, Navidea will supply clinical support services for NAV5001 on a cost-plus reimbursement basis. In consideration for the rights granted to Alseres, Navidea will also receive a milestone payment upon clearance to market NAV5001 by the U.S. FDA and a royalty on subsequent net sales of NAV5001. The Company is currently engaged in evaluating term sheets related to NAV4694.

The Company is also 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 venture, which we believe may further expand the Company's pipeline but requires less near-term funding from Navidea than the two temporarily suspended Phase 3 neurological development programs. We plan to focus our resources in 2015 primarily on increasing sales of Lymphoseek and development of products based on the Manocept platform. Although management believes that it will be able to achieve these objectives, they are subject to a number of variables beyond our control, including the nature and timing of any partnering opportunities, the ability to modify contractual commitments made in connection with these programs, and the timing and expense associated with suspension or alteration of clinical trials, and consequently we cannot assure you that we will be able to achieve our objective of bringing our expenses in line with our revenues, and we may need to seek additional debt or equity financing if we cannot achieve that objective in a timely manner.

As stated above, we believe that our current cash balance, as augmented by our recent financing with CRG, and in conjunction with projected revenue growth derived from sales of Lymphoseek, provides us with a solid foundation with which to build our business. Our capital position is further supported by the continuing availability of capital under the credit facility with Platinum, our ability to control expenses, the potential for partnership funding, and the potential to access capital markets through our shelf registration, provide us with adequate financial resources to continue to fund our business plan for the foreseeable future and enable us to reach break-even cash flow from

operations in the first quarter of 2016. However, we cannot assure you that Lymphoseek will generate our expected levels of sales and cash flow. We will continue to evaluate our time lines, strategic needs, and balance sheet requirements. We cannot assure you that if we attempt to raise additional capital through debt, royalty, equity or otherwise, we will be successful in doing so on terms acceptable to the Company, or at all. We also cannot assure you that we will be able to gain access and/or be able to execute on securing new development opportunities, successfully obtain regulatory approval for and commercialize new products, achieve significant product revenues from our products, or achieve or sustain profitability in the future.

Recent Accounting Developments

In February 2015, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2015-02, Amendments to the Consolidation Analysis. ASU 2015-02 affects reporting entities that are required to evaluate whether they should consolidate certain legal entities. All legal entities are subject to reevaluation under the revised consolidation model. Specifically, the amendments: (i) modify the evaluation of whether limited partnerships and similar legal entities are variable

interest entities (VIEs) or voting interest entities, (ii) eliminate the presumption that a general partner should consolidate a limited partnership, and (iii) affect the consolidation analysis of reporting entities that are involved with VIEs, particularly those that have fee arrangements and related party relationships. ASU 2015-02 is effective for public entities for fiscal years, and for interim periods within those fiscal years, beginning after December 15, 2015. The amendments may be applied using a modified retrospective approach or a full retrospective approach. Early adoption is permitted, including adoption in an interim period. We are currently evaluating the impact of our adoption of ASU 2015-02, however we do not expect the adoption of ASU 2015-02 to have a material effect on our consolidated financial statements upon adoption.

In April 2015, the FASB issued ASU No. 2015-03, Simplifying the Presentation of Debt Issuance Costs. ASU 2015-003 requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability rather than as an asset. The recognition and measurement guidance for debt issuance costs are not affected by ASU 2015-03. ASU 2015-03 is effective for fiscal years beginning after December 15, 2015, and interim periods within those fiscal years. Early adoption is permitted. Entities must apply the amendments in ASU 2015-03 on a retrospective basis. We do not expect the adoption of ASU 2015-03 to have a material effect on our consolidated financial statements upon adoption.

Critical Accounting Policies

We base our management's discussion and analysis of financial condition and results of operations, as well as disclosures included elsewhere in this Quarterly Report on Form 10-Q, upon our consolidated financial statements, which we have prepared in accordance with U.S. generally accepted accounting principles. We describe our significant accounting policies in the notes to the audited consolidated financial statements contained in our Annual Report on Form 10-K. We include within these policies our "critical accounting policies." Critical accounting policies are those policies that are most important to the preparation of our consolidated financial statements and require management's most subjective and complex judgment due to the need to make estimates about matters that are inherently uncertain. Changes in estimates and assumptions based upon actual results may have a material impact on our results of operations and/or financial condition.

Revenue Recognition. We currently generate revenue primarily from sales of Lymphoseek. Our standard shipping terms are FOB shipping point, and title and risk of loss passes to the customer upon delivery to a carrier for shipment from Cardinal Health's national distribution center to another point of destination. 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.

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

We also earn revenues related to our licensing and distribution agreements. The terms of these agreements may include payment to us of non-refundable upfront license fees, funding or reimbursement of research and development efforts, milestone payments if specified objectives are achieved, and/or royalties on product sales. We evaluate all deliverables within an arrangement to determine whether or not they provide value on a stand-alone basis. We recognize a contingent milestone payment as revenue in its entirety upon our achievement of a substantive milestone if the consideration earned from the achievement of the milestone (i) is consistent with performance required to

achieve the milestone or the increase in value to the delivered item, (ii) relates solely to past performance and (iii) is reasonable relative to all of the other deliverables and payments within the arrangement.

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

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

Use of Estimates. The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. We base these estimates and assumptions upon historical experience and existing, known circumstances. Actual results could differ from those estimates. Specifically, management may make significant estimates in the following areas:

Stock-Based Compensation. Stock-based payments to employees and directors, including grants of stock options and restricted stock, are recognized in the statements of operations based on their estimated fair values on the date of grant. The fair value of each option award is estimated on the date of grant using the Black-Scholes option pricing model to value share-based payments and the portion that is ultimately expected to vest is recognized as compensation expense over either (1) the requisite service period or (2) the estimated performance period. The determination of fair value using the Black-Scholes option pricing model is affected by our stock price as well as assumptions regarding a number of complex and subjective variables, including expected stock price volatility, risk-free interest rate, expected dividends and projected employee stock option behaviors. We estimate the expected term based on the contractual term of the awards and employees' exercise and expected post-vesting termination behavior. The restricted stock awards are valued based on the closing stock price on the date of grant and amortized ratably over the estimated life of the award.

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

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

Fair Value of Derivative Instruments. Derivative instruments embedded in contracts, to the extent not already a free-standing contract, are bifurcated and accounted for separately. All derivatives are recorded on the consolidated balance sheets at fair value in accordance with current accounting guidelines for such complex financial instruments. Unrealized gains and losses on the derivatives are classified in other expenses as a change in derivative liabilities in the consolidated statements of operations. We do not use derivative instruments for hedging of market risks or for trading or speculative purposes.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk. As of March 31, 2015, our \$4.9 million in cash was primarily invested in interest-bearing money market accounts. Due to the low interest rates being realized on these accounts, we believe that a hypothetical 10% increase or decrease in market interest rates would not have a material impact on our consolidated financial position, results of operations or cash flows.

We also have exposure to changes in interest rates on our variable-rate debt obligations. As of March 31, 2015, the interest rate on certain of our debt obligations was based on the U.S. prime rate. Based on the amount of our variable-rate borrowings at March 31, 2015, which totaled approximately \$6.2 million, an immediate one percentage point increase in the U.S. prime rate would increase our annual interest expense by approximately \$62,000. This estimate assumes that the amount of variable rate borrowings remains constant for an annual period and that the interest rate change occurs at the beginning of the period. Because our debt obligations are currently subject to the minimum interest rates defined in the loan agreements, a decrease in the U.S. prime rate would not affect our annual interest expense.

Foreign Currency Exchange Rate Risk. We do not currently have material foreign currency exposure related to our assets as the majority are denominated in U.S. currency and our foreign-currency based transaction exchange risk is not material. For

the three months ended March 31, 2015 and 2014, we recorded foreign currency transaction gains of approximately \$28,000 and \$2,000, respectively.

Equity Price Risk. We do not use derivative instruments for hedging of market risks or for trading or speculative purposes. Derivative instruments embedded in contracts, to the extent not already a free-standing contract, are bifurcated and accounted for separately. All derivatives are recorded on the consolidated balance sheet at fair value in accordance with current accounting guidelines for such complex financial instruments. The fair value of our warrant liabilities is determined using various inputs and assumptions, several of which are based on a survey of peer group companies since the warrants are exercisable for common stock of a non-public subsidiary company. As of March 31, 2015, we had approximately \$63,000 of derivative liabilities recorded on our balance sheet related to outstanding MT warrants. Due to the relatively low valuation of the MT warrants, a hypothetical 50% change in our stock price would not have a material effect on the consolidated financial statements.

Item 4. Controls and Procedures

Disclosure Controls and Procedures

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

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Exchange Act) as of March 31, 2015. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive and principal financial officers, as appropriate, to allow timely decisions regarding required disclosure. Based on our evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of the end of the period covered by this report, our disclosure controls and procedures are adequately designed and are effective.

Our management, including our Chief Executive Officer and Chief Financial Officer, understands that our disclosure controls and procedures do not guarantee that all errors and all improper conduct will be prevented. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute assurance that the objectives of the control system are met. Further, a design of a control system must reflect the fact that there are resource constraints, and the benefit of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of improper conduct, if any, have been detected. These inherent limitations include the realities that judgments and decision-making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more persons, or by management override of the control. Further, the design of any system of controls is also based in part upon assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations of a cost-effective control system, misstatements due to error or fraud may occur and may not be detected.

Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles, and includes those policies and procedures that:

- pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Company;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles and that receipts and expenditures of the Company are being made only in accordance with authorization of management and directors of the Company; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on the financial statements.

Changes in Control Over Financial Reporting

During the quarter ended March 31, 2015, there were no changes in our internal control over financial reporting that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

31

PART II - OTHER INFORMATION

Item 1A. Risk Factors

There have been no material changes to the Company's risk factors as previously reported in the Company's Annual Report on Form 10-K for the year ended December 31, 2014, filed with the SEC on March 16, 2015.

Item 2. Unregistered Sales of Equity Securities

During the three-month period ended March 31, 2015, we issued 36,839 shares of our common stock to certain members of our Board of Directors as payment in lieu of a portion of their fourth quarter 2014 compensation. The issuance of these securities was exempt from registration under Section 4(2) of the Securities Act and Regulation D promulgated thereunder.

On March 11, 2015 our subsidiary Macrophage Therapeutics, Inc. (MT) issued ten shares of its Series A Convertible Preferred Stock (MT Preferred Stock) and warrants to purchase 300 shares of its common stock (MT Warrants) to two investors. Each share of MT Preferred Stock is convertible at the option of the holder into 30 shares of the common stock of MT, subject to adjustment for stock splits, combinations, recapitalizations, dividends or other distributions, and certain reorganizations. Pursuant to the terms of a Securities Exchange Agreement between the Company and the investors, the investors have an option to exchange their MT Preferred Stock for common stock of the Company in the event that MT has not completed a public offering with gross proceeds to MT of at least \$50 million by the second anniversary of the closing of the initial sale of MT Preferred Stock, at an exchange rate per share obtained by dividing \$50,000 by the greater of (i) 80% of the twenty-day volume weighted average price per share of our common stock on the second anniversary of the initial closing or (ii) \$3.00. To the extent that the investors do not timely exercise their exchange right, MT has the right to redeem their MT Preferred Stock for a price equal to \$58,320 per share. Proceeds of \$500,000 from the sale of these securities are to be used for MT's development programs and general working capital. The issuance of these securities was exempt from registration under Section 4(2) of the Securities Act and Regulation D promulgated thereunder.

Item 6. Exhibits

- 10.1 Navidea Biopharmaceuticals, Inc. 2014 Stock Incentive Plan (as amended March 3, 2015).*
- 10.2 Securities Exchange Agreement dated as of March 11, 2015 among Macrophage Therapeutics, Inc., Platinum-Montaur Life Sciences, LLC and Michael Goldberg, M.D.*
- 31.1 Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*
- 31.2 Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*
- 32.1 Certification of Chief Executive Officer of Periodic Financial Reports pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350.**
- 32.2 Certification of Chief Financial Officer of Periodic Financial Reports pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350.**
- 101.INS XBRL Instance Document*
- 101.SCH XBRL Taxonomy Extension Schema Document*
- 101.CAL XBRL Taxonomy Extension Calculation Linkbase Document*
- 101.DEF XBRL Taxonomy Extension Definition Linkbase Document*
- 101.LAB XBRL Taxonomy Extension Label Linkbase Document*
- 101.PRE XBRL Taxonomy Extension Presentation Linkbase Document*

* Filed herewith.

** Furnished herewith.

Items 1, 3, 4 and 5 are not applicable and have been omitted.

SIGNATURES

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

NAVIDEA BIOPHARMACEUTICALS, INC.
(the Company)
May 11, 2015

By: /s/ Ricardo J. Gonzalez

Ricardo J. Gonzalez
President and Chief Executive Officer
(duly authorized officer; principal executive officer)

By: /s/ Brent L. Larson

Brent L. Larson
Executive Vice President and Chief Financial Officer
(principal financial and accounting officer)

INDEX TO EXHIBITS

- 10.1 Navidea Biopharmaceuticals, Inc. 2014 Stock Incentive Plan (as amended March 3, 2015).*
- 10.2 Securities Exchange Agreement dated as of March 11, 2015 among Macrophage Therapeutics, Inc., Platinum-Montaur Life Sciences, LLC and Michael Goldberg, M.D.*
- 31.1 Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*
- 31.2 Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*
- 32.1 Certification of Chief Executive Officer of Periodic Financial Reports pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350.**
- 32.2 Certification of Chief Financial Officer of Periodic Financial Reports pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350.**
- 101.INS XBRL Instance Document*
- 101.SCH XBRL Taxonomy Extension Schema Document*
- 101.CAL XBRL Taxonomy Extension Calculation Linkbase Document*
- 101.DEF XBRL Taxonomy Extension Definition Linkbase Document*
- 101.LAB XBRL Taxonomy Extension Label Linkbase Document*
- 101.PRE XBRL Taxonomy Extension Presentation Linkbase Document*

* Filed herewith.

** Furnished herewith.