NAVIDEA BIOPHARMACEUTICALS, INC.
Form 10-Q
November 09, 2015

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended September 30, 2015

o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to to

Commission File Number: 001-35076

NAVIDEA BIOPHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	31-1080091
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)

5600 Blazer Parkway, Suite 200, Dublin, Ohio	43017-7550
(Address of principal executive offices)	(Zip Code)

(614) 793-7500

(Registrant’s telephone number, including area code)

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No o

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

Large accelerated filer ¨	Accelerated filer x
Non-accelerated filer ¨	Smaller reporting company ¨

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

Indicate the number of shares outstanding of each of the issuer’s classes of common stock, as of the latest practicable date: 155,699,665 shares of common stock, par value $.001 per share (as of the close of business on November 2, 2015).

NAVIDEA BIOPHARMACEUTICALS, INC. AND SUBSIDIARIES

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PART I – FINANCIAL INFORMATION

Item 1. Financial Statements

Navidea Biopharmaceuticals, Inc. and Subsidiaries

Consolidated Balance Sheets

	September 30, 2015 (unaudited)	December 31, 2014
ASSETS		
Current assets:		
Cash	$11,370,420	$5,479,006
Accounts receivable, net	1,909,372	816,544
Inventory, net	877,183	932,385
Prepaid expenses and other	807,687	1,371,210
Total current assets	14,964,662	8,599,145
Property and equipment	3,862,440	4,124,028
Less accumulated depreciation and amortization	1,805,113	1,614,320
	2,057,327	2,509,708
Patents and trademarks	233,596	219,558
Less accumulated amortization	45,701	38,725
	187,895	180,833
Investment in R-NAV, LLC	—	241,575
Other assets	273,573	299,047
Total assets	$17,483,457	$11,830,308
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$1,298,879	$1,477,499
Accrued liabilities and other	3,602,891	3,234,120
Deferred revenue, current	1,002,531	—
Notes payable, current, net of discounts of $0 and $863,813, respectively	333,333	4,348,678
Total current liabilities	6,237,634	9,060,297
Deferred revenue	416,667	—
Notes payable, net of discounts of $2,102,947 and $1,585,882, respectively	60,946,844	29,484,057
Other liabilities	1,701,939	3,089,420
Total liabilities	69,303,084	41,633,774
Commitments and contingencies		
Stockholders' deficit:		
Preferred stock; $.001 par value; 5,000,000 shares authorized; 0 and 4,519 Series B shares issued and outstanding at September 30, 2015 and December 31, 2014, respectively	—	4

Common stock; $.001 par value; 200,000,000 shares authorized; 150,703,485 and 150,200,259 shares issued and outstanding at September 30, 2015 and December 31, 2014,respectively	150,703	150,200
Additional paid-in capital	325,596,476	323,030,301
Accumulated deficit	(378,036,538)	(352,983,971)
Total Navidea stockholders' deficit	(52,289,359)	(29,803,466)
Noncontrolling interest	469,732	—
Total stockholders’ deficit	(51,819,627)	(29,803,466)
Total liabilities and stockholders’ deficit	$17,483,457	$11,830,308

See accompanying notes to consolidated financial statements (unaudited).

Navidea Biopharmaceuticals, Inc. and Subsidiaries

Consolidated Statements of Operations

(unaudited)

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2015	2014	2015	2014
Revenue:				
Lymphoseek sales revenue	$2,952,522	$1,101,071	$6,751,492	$2,773,959
Lymphoseek license revenue	550,000	300,000	883,333	300,000
Grant and other revenue	476,755	848,999	1,320,816	1,002,605
Total revenue	3,979,277	2,250,070	8,955,641	4,076,564
Cost of goods sold	457,590	807,880	1,239,377	1,271,598
Gross profit	3,521,687	1,442,190	7,716,264	2,804,966
Operating expenses:				
Research and development	3,902,155	4,158,085	10,180,517	14,496,977
Selling, general and administrative	3,942,609	2,646,591	13,485,576	11,465,076
Total operating expenses	7,844,764	6,804,676	23,666,093	25,962,053
Loss from operations	(4,323,077)	(5,362,486)	(15,949,829)	(23,157,087)
Other income (expense):				
Interest expense, net	(2,148,369)	(918,026)	(4,690,686)	(2,764,122)
Equity in loss of R-NAV, LLC	(26,785)	(262,198)	(295,217)	(262,198)
Change in fair value of financial instruments	(1,577,275)	(409,650)	(1,702,902)	(109,499)
Loss on extinguishment of debt	—	—	(2,440,714)	(2,610,196)
Other, net	4,402	53,464	26,100	41,419
Total other income (expense), net	(3,748,027)	(1,536,410)	(9,103,419)	(5,704,596)
Net loss	(8,071,104)	(6,898,896)	(25,053,248)	(28,861,683)
Less loss attributable to noncontrolling interest	(340)	—	(681)	—
Deemed dividend on beneficial conversion feature of MT Preferred Stock	—	—	(46,000)	—
Net loss attributable to common stockholders	$(8,070,764)	$(6,898,896)	$(25,098,567)	$(28,861,683)
Loss per common share (basic and diluted)	$(0.05)	$(0.05)	$(0.17)	$(0.19)
Weighted average shares outstanding (basic and diluted)	150,186,131	150,169,712	150,030,638	148,344,064

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 stock upon exercise of stock options, net	—	—	124,238	124	54,206	—	—	54,330
Issued restricted stock	—	—	354,000	354	—	—	—	354
Canceled forfeited restricted stock	—	—	(108,000)	(108)	108	—	—	—
Canceled stock to pay employee tax obligations	—	—	(7,645)	(7)	(12,607)	—	—	(12,614)
Issued stock in payment of Board retainers	—	—	72,476	72	131,189	—	—	131,261
Issued stock to 401(k) plan	—	—	68,157	68	117,031	—	—	117,099
Exchanged Series B Preferred Stock for warrants	(4,519)	(4)	—	—	4	—	—	—
Extension of warrant expiration	—	—	—	—	149,615	—	—	149,615

date								
Issued warrants in connection with advisory services agreement	—	—	—	—	256,450	—	—	256,450
Stock compensation expense	—	—	—	—	1,916,179	—	—	1,916,179
Net loss	—	—	—	—	—	(25,052,567)	(681)	(25,053,248)
Issuance of MT Preferred Stock, net of deemed dividend on beneficial conversion feature	—	—	—	—	(46,000)	—	470,413	424,413
Balance, September 30, 2015	—	$—	150,703,485	$150,703	$325,596,476	$(378,036,538)	$469,732	$(51,819,627)

See accompanying notes to consolidated financial statements (unaudited).

Navidea Biopharmaceuticals, Inc. and Subsidiaries

Consolidated Statements of Cash Flows

(unaudited)

	Nine Months Ended September 30,	
	2015	2014
Cash flows from operating activities:		
Net loss	$(25,053,248)	$(28,861,683)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	431,368	360,702
Loss on disposal and abandonment of assets	33,184	31,794
Change in reserve for uncollectible accounts	16,000	—
Change in inventory reserve and other adjustments to inventory	138,914	539,027
Amortization of debt discount and issuance costs	423,522	637,565
Compounded interest on long term debt	1,231,125	—
Stock compensation expense	1,916,179	1,032,244
Equity in loss of R-NAV, LLC	295,217	262,198
Change in fair value of financial instruments	1,702,902	109,499
Loss on extinguishment of debt	2,440,714	2,610,196
Issued stock to 401(k) plan for employer matching contributions	117,099	100,044
Extension of warrant expiration date	149,615	—
Issued warrants in connection with advisory services agreement	256,450	—
Other	77,620	—
Changes in operating assets and liabilities:		
Accounts receivable	(1,108,828)	(314,800)
Inventory	(83,712)	573,191
Prepaid expenses and other assets	588,996	(109,116)
Accounts payable	(178,620)	(45,410)
Accrued and other liabilities	305,170	(1,226,288)
Deferred revenue	1,419,198	—
Net cash used in operating activities	(14,881,135)	(24,300,837)
Cash flows from investing activities:		
Purchases of equipment	(30,406)	(1,111,418)
Proceeds from sales of equipment	38,265	—
Patent and trademark costs	(27,092)	(51,876)
Investment in R-NAV, LLC	—	(333,334)
Net cash used in investing activities	(19,233)	(1,496,628)
Cash flows from financing activities:		
Proceeds from issuance of MT Preferred Stock and warrants	500,000	—
Payment of issuance costs related to MT Preferred Stock and warrants	(12,587)	—
Proceeds from issuance of common stock and short swing profits	65,975	87,982
Payment of tax withholdings related to stock-based compensation	(23,906)	(75,759)
Proceeds from notes payable	54,500,000	30,000,000
Payment of debt-related costs	(3,902,487)	(1,763,526)
Principal payments on notes payable	(30,333,333)	(25,000,000)

Payments under capital leases	(1,880)	(1,640)
Net cash provided by financing activities	20,791,782	3,247,057
Net increase (decrease) in cash	5,891,414	(22,550,408)
Cash, beginning of period	5,479,006	32,939,026
Cash, end of period	$11,370,420	$10,388,618

See accompanying notes to consolidated financial statements (unaudited).

Notes to the Consolidated Financial Statements (unaudited)

1. Summary of Significant Accounting Policies

a. Basis of Presentation: The information presented as of September 30, 2015 and for the three-month and nine-month periods ended September 30, 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 September 30, 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, LLC (R-NAV) is being accounted for using the equity method of accounting and is therefore not consolidated.

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

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

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

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

A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement. In determining the appropriate levels, we perform a detailed analysis of the assets and liabilities whose fair value is measured on a recurring basis. At each reporting period, all assets and liabilities for which the fair value measurement is based on significant unobservable inputs or instruments which trade infrequently and therefore have little or no price transparency are classified as Level 3. See Note 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 September 30, 2015 and December 31, 2014 primarily consists of the face amount of the notes less unamortized discounts. See Note 8. At September 30, 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 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 September 30, 2015, the fair value of our notes payable is approximately $64.2 million, compared to the carrying value of $61.3 million.

(3) Derivative liabilities: Derivative liabilities are related to certain outstanding warrants which are recorded at fair value. Derivative liabilities totaling $63,000 as of September 30, 2015 were included in other liabilities on the consolidated balance sheets. No derivative liabilities were outstanding as of December 31, 2014. The assumptions used to calculate fair value as of September 30, 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 Notes 2 and 6.

c. Revenue Recognition: We currently generate revenue primarily from sales of Lymphoseek® (technetium Tc 99m tilmanocept) injection. Our standard shipping terms are FOB shipping point, and title and risk of loss passes to the

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

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

We also earn revenues related to our licensing and distribution agreements. The terms of these agreements may include payment to us of non-refundable upfront license fees, funding or reimbursement of research and development efforts, milestone payments if specified objectives are achieved, and/or royalties on product sales. We evaluate all deliverables within an arrangement to determine whether or not they provide value on a stand-alone basis. We recognize a contingent milestone payment as revenue in its entirety upon our achievement of a substantive milestone if the consideration earned from the achievement of the milestone (i) is consistent with performance required to achieve the milestone or the increase in value to the delivered item, (ii) relates solely to past performance and (iii) is reasonable relative to all of the other deliverables and payments within the arrangement. We received a non-refundable upfront cash payment of $2.0 million from SpePharm AG upon execution of the SpePharm License Agreement in March 2015. We have determined that the license and other non-contingent deliverables do not have stand-alone value because the license could not be deemed to be fully delivered for its intended purpose unless we perform our other obligations, including specified development work. Accordingly, they do not meet the separation criteria, resulting in these deliverables being considered a single unit of account. As a result, revenue relating to the upfront cash payment was deferred and is being recognized on a straight-line basis over the estimated obligation period of two years.

We generate additional revenue from grants to support various product development initiatives. We generally recognize grant revenue when expenses reimbursable under the grants have been paid and payments under the grants become contractually due. Lastly, we recognize revenues from the provision of services to R-NAV and its subsidiaries. See Note 7.

d. Change in Accounting Principle: In April 2015, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2015-03, Simplifying the Presentation of Debt Issuance Costs. ASU 2015-03 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.

During the second quarter of 2015, the Company elected early adoption of ASU 2015-03. The consolidated balance sheet as of December 31, 2014 has been adjusted to reflect retrospective application of the new method of presentation. Deferred debt issuance costs totaling $90,000 that were included in other assets as of December 31, 2014 were reclassified as discounts on notes payable, current, of $35,000 and discounts on notes payable, long term, of $55,000. We have reflected these unamortized costs as a reduction of the debt on the balance sheet as of September 30, 2015 and will continue to do so in future periods. The adoption of ASU 2015-03 had no impact on the consolidated statements of operations, stockholders' deficit or cash flows.

e. Recent Accounting Pronouncements: In February 2015, the FASB issued 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 July 2015, the FASB issued ASU No. 2015-11, Simplifying the Measurement of Inventory. ASU 2015-11 applies to all inventory that is measured using methods other than last-in, first-out or the retail inventory method, including inventory that is measured using first-in, first-out or average cost. ASU 2015-11 requires entities to measure inventory at the lower of cost and net realizable value, defined as the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. ASU 2015-11 is effective for public entities for fiscal years beginning after December 15, 2016, and interim periods with fiscal years beginning after December 15, 2017. The amendments in ASU 2015-11 should be applied prospectively with earlier application permitted as of the beginning of an interim or annual reporting period. We do not expect the adoption of ASU 2015-11 to have a material effect on our consolidated financial statements upon adoption.

In August 2015, the FASB issued ASU No. 2015-14, Revenue from Contracts with Customers. ASU 2015-14 defers the effective date of ASU No. 2014-09 for all entities by one year. Public business entities should adopt the new revenue recognition standard for annual reporting periods beginning after December 15, 2017, including interim periods within that year. Early adoption is permitted only as of annual reporting periods beginning after December 15, 2016, including interim periods within that year. We are evaluating the potential impact of the adoption of ASU 2014-09, but we do not currently expect the adoption to have a material effect on our consolidated financial statements upon adoption.

2. Fair Value

As discussed in Note 8, under the First and Second Amended Platinum Notes, Platinum-Montaur Life Sciences, LLC (Platinum) had 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 into Navidea common stock, under certain circumstances. In May 2015, Navidea and Platinum executed a Third Amended Platinum Note, which extends Platinum's right to convert any portion of the unpaid principal or unpaid interest to all draws under the credit facility, including those made prior to the second quarter of 2013. The Third Amended Platinum Note also changed other provisions of the Platinum Loan Agreement as discussed further in Note 8. Platinum’s debt instrument, including the embedded option to convert such debt into common stock, is recorded at fair value on the consolidated balance sheets. The estimated fair value of the Platinum notes payable is $12.3 million at September 30, 2015.

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. The warrants have certain characteristics including a net settlement provision that require the warrants 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 September 30, 2015, and will continue to be measured on a recurring basis. See Notes 1(b)(3) and 6.

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

Liabilities Measured at Fair Value on a Recurring Basis as of September 30, 2015				
Description	Quoted Prices in Active Markets for Identical Liabilities	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total

	(Level 1)			
Platinum notes payable	$ —	$ —	$ 12,280,513	$12,280,513
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

a. 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.

b. Sensitivity Analysis-Level 3 Measurements: Changes in the Company's current internal estimates and forecasts are likely to cause material changes in the fair value of certain liabilities. The significant unobservable inputs used in the fair value measurement of the liabilities include the amount and timing of future draws expected to be taken under the Platinum Loan Agreement based on current internal forecasts. 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 and nine-month periods ended September 30, 2015 and 2014. There were no transfers in or out of our Level 2 liabilities during the three-month and nine-month periods ended September 30, 2015 or 2014. Changes in the estimated fair value of our Level 3 liabilities relating to unrealized gains (losses) are recorded as changes in fair value of financial instruments in the consolidated statements of operations. The change in the estimated fair value of our Level 3 liabilities during the three-month periods ended September 30, 2015 and 2014 was $1.6 million and $410,000, respectively. The change in the estimated fair value of our Level 3 liabilities during the nine-month periods ended September 30, 2015 and 2014 was $1.7 million and $109,000, respectively.

3. Stock-Based Compensation

At September 30, 2015, we have instruments outstanding under two stock-based compensation plans; the Amended and Restated 2002 Stock Incentive Plan (the 2002 Plan) and the Amended and Restated 2014 Stock Incentive Plan (the 2014 Plan). Total shares authorized under each plan are 12 million shares and 5 million shares, respectively. 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. 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 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 September 30, 2015 and 2014, our total stock-based compensation expense, which includes reversals of expense for certain forfeited or cancelled awards, was approximately $397,000 and $(528,000), respectively. For the nine-month periods ended September 30, 2015 and 2014, our total stock-based compensation expense was approximately $1.9 million and $1.0 million, respectively. We have not recorded any income tax benefit related to stock-based compensation in either of the three-month and nine-month periods ended September 30, 2015 and 2014.

A summary of the status of our stock options as of September 30, 2015, and changes during the nine-month period then ended, is presented below:

	Nine Months Ended September 30, 2015			
	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value
Outstanding at beginning of period	5,345,764	$ 2.16		
Granted	1,365,400	1.67		
Exercised	(146,625)	0.61		
Canceled and Forfeited	(1,081,725)	2.82		
Expired	(5,750)	1.26		
Outstanding at end of period	5,477,064	$ 1.95	7.4 years	$3,058,790
Exercisable at end of period	2,222,049	$ 2.21	5.3 years	$1,012,990

A summary of the status of our unvested restricted stock as of September 30, 2015, and changes during the nine-month period then ended, is presented below:

	Nine Months Ended September 30, 2015	
	Number of Shares	Weighted Average Grant-Date Fair Value
Unvested at beginning of period	498,250	$ 1.91
Granted	354,000	1.73
Vested	(240,750)	1.85
Forfeited	(108,000)	2.71
Unvested at end of period	503,500	$ 1.63

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. In May 2015, 100,750 shares of restricted stock held by employees with an aggregate fair value of $130,000 vested as scheduled according to the terms of the restricted stock agreements.

As of September 30, 2015, there was approximately $1.5 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 1.7 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 and nine-month periods ended September 30, 2015 and 2014 excludes the effects of 19.3 million and 17.7 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, 503,500 shares of unvested restricted stock for the three-month and nine-month periods ended September 30, 2015, and 563,500 shares of unvested restricted stock for the three-month and nine-month periods ended September 30, 2014, respectively, were excluded in determining basic and diluted loss per share 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 September 30, 2015 and December 31, 2014, net of reserves of $352,000 and $539,000, respectively, are as follows:

	September 30, 2015 (unaudited)	December 31, 2014
Materials	$396,000	$—
Work-in-process	236,422	1,034,476
Finished goods	596,450	436,936
Reserves	(351,689)	(539,027)
Total	$877,183	$932,385

During the nine-month period ended September 30, 2015, we capitalized $810,000 of inventory costs associated with our Lymphoseek product. The Company capitalized no such costs during the same period in 2014. During the nine-month period ended September 30, 2015, we wrote off $120,000 of materials related to production issues. During the nine-month periods ended September 30, 2015 and 2014, we utilized $184,000 and $121,000, 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 (collectively, the Investors) 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 that may 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 the 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.

The warrants have certain characteristics including a net settlement provision that require the warrants to be accounted for as a derivative liability at fair value, with subsequent changes in fair value included in earnings. The fair value of the warrants was estimated to be $63,000 at issuance and at September 30, 2015. See Notes 1(b)(3) and 2. In addition, the MT Preferred Stock includes 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 31% is being accounted for using the equity method of accounting. Navidea's equity in the loss of R-NAV was $27,000 and $262,000, respectively, for the three-month periods ended September 30, 2015 and 2014. Navidea's equity in the loss of R-NAV was $295,000 and $262,000, respectively, for the nine-month periods ended September 30, 2015 and 2014.

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 $27,000 and $21,000, respectively, of in-kind services during the three-month periods ended September 30, 2015 and 2014. The Company provided $54,000 and $21,000, respectively, of in-kind services during the nine-month periods ended September 30, 2015 and 2014. As of September 30, 2015, the Company has $408,000 of in-kind services remaining to provide under this obligation.

8. Notes Payable

Capital Royalty Group Debt

In May 2015, Navidea and its subsidiary Macrophage Therapeutics, Inc., as guarantor, executed a Term Loan Agreement (the CRG Loan Agreement) with Capital Royalty Partners II L.P. in its capacity as a lender and as control agent for other affiliated lenders party to the CRG Loan Agreement (collectively, the Lenders) in which the Lenders agreed to make a term loan to the Company in the aggregate principal amount of $50 million (the CRG Term Loan), with an additional $10 million in loans to be made available upon the satisfaction of certain conditions stated in the CRG Loan Agreement. Closing and funding of the CRG Term Loan occurred on May 15, 2015 (the Effective Date). The principal balance of the CRG Term Loan will bear interest from the Effective Date at a per annum rate of interest equal to 14.0%. Through March 31, 2019, the Company has the option of paying (i) 10.00% of the per annum interest in cash and (ii) 4.00% of the per annum interest as compounded interest which is added to the aggregate principal amount of the CRG Term Loan. During the nine-month period ended September 30, 2015, $769,000 of interest was compounded and added to the balance of the CRG Term Loan. In addition, the Company began paying the cash portion of the interest in arrears on June 30, 2015. Principal is due in eight equal quarterly installments during the final two years of the term. All unpaid principal, and accrued and unpaid interest, is due and payable in full on March 31, 2021. As of September 30, 2015, the outstanding principal balance of the CRG Term Loan was $50.8 million.

The Company may voluntarily prepay the CRG Term Loan in full, upon fifteen business days' prior written notice to the Lenders, with a prepayment premium beginning at 5% and declining by 1% annually thereafter, with no premium being payable if prepayment occurs after the fifth year of the term. The CRG Term Loan required the payment on the borrowing date of a financing fee of $625,000 which was recorded as a discount to the debt. In addition, a facility fee of $1.0 million is payable at the end of the term or when the loan is repaid in full. A long-term liability has been recorded for the $1.0 million facility fee with a corresponding discount to the debt. The CRG Term Loan is 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 financial reporting requirements and a prohibition against the incurrence of indebtedness, or creation of additional liens, other than as specifically permitted by the terms of the CRG Loan Agreement. The Lenders may accelerate the payment terms of the CRG Loan Agreement upon the occurrence of certain events of default set forth therein, which include the failure of the Company to make timely payments of amounts due under the CRG Loan Agreement, the failure of the Company to adhere to the covenants set forth in the CRG Loan Agreement, and the insolvency of the

Company. The covenants of the CRG Loan Agreement include a covenant that the Company shall have EBITDA of no less than $5 million in each calendar year during the term or revenues from sales of Lymphoseek in each calendar year during the term of at least $11 million in 2015, with the target minimum revenue increasing in each year thereafter until reaching $45 million in 2020. The Company believes it is still possible to achieve the level of sales required to maintain compliance with the sales covenant. However, if the Company were to fail to meet the applicable minimum EBITDA or revenue target in any calendar year, the CRG Loan Agreement provides the Company a cure right if it raises 2.5 times the EBITDA or revenue shortfall in equity or subordinated debt and deposits such funds in a separate blocked account. The Company is confident it has the ability to access the capital necessary to cure any potential shortfall for 2015. Additionally, the Company must maintain liquidity, defined as the balance of unencumbered cash and permitted cash equivalent investments, of at least $5 million during the term of the CRG Term Loan. The events of default under the CRG Loan Agreement also include a failure of Platinum to perform its funding obligations under the Platinum Loan Agreement (as defined below) at any time as to which the Company had negative EBITDA for the most recent fiscal quarter, as a result either of Platinum’s repudiation of its obligations under the Platinum Loan Agreement, or the occurrence of an insolvency event with respect to Platinum. As of September 30, 2015, we were in compliance with all applicable covenants of the CRG Loan Agreement.

In connection with the CRG Loan Agreement, the Company recorded a debt discount related to lender fees and other costs directly attributable to the CRG Loan Agreement totaling $2.2 million. The debt discount is being amortized as non-cash interest expense using the effective interest method over the term of the CRG Loan Agreement. As of September 30, 2015, the balance of the debt discount was $2.1 million.

Oxford Debt

In March 2014, we executed a Loan and Security Agreement (the Oxford Loan Agreement) with Oxford Finance, LLC (Oxford), providing for a loan to the Company of $30 million. Pursuant to the Oxford Loan Agreement, we issued Oxford: (1) Term Notes in the aggregate principal amount of $30 million, bearing interest at 8.5% (the Oxford Notes), and (2) Series KK warrants to purchase an aggregate of 391,032 shares of our common stock at an exercise price of $1.918 per share, expiring in March 2021 (the Series KK warrants). We began making monthly payments of interest only on April 1, 2014, and monthly payments of principal and interest beginning April 1, 2015. In May 2015, in connection with the consummation of the CRG Loan Agreement, the Company repaid all amounts outstanding under the Oxford Loan Agreement. The payoff amount of $31.6 million included payments of $289,000 as a pre-payment fee and $2.4 million as an end-of-term final payment fee. The carrying value of the Oxford Notes was $26.9 million prior to payoff. We recorded a loss on extinguishment of the Oxford Notes of $2.4 million.

Platinum Credit Facility

In connection with the Company entering into the CRG Loan Agreement, the Company and Platinum entered into a Third Amendment (the Third Platinum Amendment) to the Loan Agreement between the Company and Platinum, dated July 25, 2012, as amended June 25, 2013 and March 4, 2014 (the Platinum Loan Agreement). Platinum and the Lenders also entered into a Subordination Agreement (the Subordination Agreement), which the Company consented to and acknowledged, providing for the subordination of the Company's indebtedness to Platinum under the Platinum Loan Agreement to the Company's indebtedness under the CRG Loan Agreement, among other customary terms and conditions. Contemporaneously with the execution of the Third Platinum Amendment, the Company delivered a Third Amended and Restated Promissory Note, dated the Effective Date (the Third Amended Platinum Note), which amends and restates the Second Amended Promissory Note, dated March 4, 2014, made by the Company in favor of Platinum in the original principal amount of up to $35 million. Among other things, the Third Platinum Amendment (i) extends the term of the Platinum Loan Agreement until September 30, 2021 or six months following an early repayment of the CRG Term Loan; (ii) changes the interest rate to the greater of (a) the United States prime rate as reported in The Wall Street Journal plus 6.75%, (b) 10.0% or (c) the highest rate of interest then payable pursuant to the CRG Term Loan plus 0.125% (the effective interest rate as of September 30, 2015 was 14.125%); (iii) requires such interest to compound monthly; and (iv) changes the provisions of the Platinum Loan Agreement governing Platinum's right to convert advances into common stock of the Company. The Third Platinum Amendment provides for the conversion of all principal and interest outstanding under the Platinum Loan Agreement, but not until such time as the average daily volume weighted average price of the Company's common stock for the ten preceding trading days exceeds $2.53 per share.

The Platinum Loan Agreement provides us with a credit facility of up to $50 million. The Company borrowed an additional $4.5 million under the Platinum Loan Agreement during the nine-month period ended September 30, 2015. In addition, $462,000 of interest was compounded and added to the balance of the Third Amended Platinum Note during the nine-month period ended September 30, 2015. The Third Amended Platinum Note is reflected on the consolidated balance sheets at its estimated fair value, which includes the estimated fair value of the embedded conversion option of $4.1 million. Changes in the estimated fair value of the Third Amended Platinum Note of $1.6 million and $402,000, respectively, were recorded as non-cash changes in fair value of financial instruments during the three-month periods ended September 30, 2015 and 2014. Changes in the estimated fair value of the Third Amended Platinum Note of $1.7 million and $104,000, respectively, were recorded as non-cash changes in fair value of financial instruments during the nine-month periods ended September 30, 2015 and 2014. The estimated fair value of the Third Amended Platinum Note was $12.3 million as of September 30, 2015. As of September 30, 2015, the

outstanding principal balance of the Third Amended Platinum Note was approximately $8.2 million, with $27.3 million currently available under the credit facility. An additional $15 million is potentially available under the credit facility on terms to be negotiated.

R-NAV Debt

In July 2015, we made a principal payment on the note payable to R-NAV of $333,333. As of September 30, 2015, the outstanding principal balance of the note payable to R-NAV was $333,333 which is due in July 2016.

Interest on our Debt

During the three-month periods ended September 30, 2015 and 2014, we recorded interest expense of $2.2 million and $921,000, respectively, related to our notes payable. Of these amounts, $65,000 and $201,000, respectively, related to amortization of the debt discounts related to our notes payable. An additional $802,000 of total interest expense was compounded and added to the balance of our notes payable during the three-month period ended September 30, 2015. During the nine-month periods ended September 30, 2015 and 2014, we recorded interest expense of $4.7 million and $2.8 million, respectively, related to our notes payable. Of these amounts, $424,000 and $638,000, respectively, related to amortization of the debt discounts related to our notes payable. An additional $1.2 million of total interest expense was compounded and added to the balance of our notes payable during the nine-month period ended September 30, 2015.

9. Equity

During the nine-month period ended September 30, 2015, we issued 72,476 shares of our common stock valued at $131,000 to certain members of our Board of Directors as payment in lieu of cash for a portion of their fourth quarter 2014 and second quarter 2015 compensation.

10. Stock Warrants

In July 2015, we extended the expiration date of our outstanding Series BB warrants by three years to July 2018. The modification of the Series BB warrant expiry resulted in recording a non-cash selling, general and administrative expense of approximately $150,000 during the three-month period ended September 30, 2015.

In August 2015, we entered into a Securities Exchange Agreement with two investment funds managed by Platinum Management (NY) LLC to exchange the 4,519 shares of Series B Convertible Preferred Stock (Preferred Stock) held by them for twenty-year warrants to purchase common stock of the Company (the Series LL warrants). The Preferred Stock was convertible into common stock at a conversion rate of 3,270 shares of common stock per share of Preferred Stock resulting in an aggregate number of shares of common stock into which the Preferred Stock was convertible of 14,777,130 shares. The exercise price of the Series LL warrants is $0.01 per share, and the total number of shares of common stock for which the Series LL warrants are exercisable is 14,777,130 shares. The Series LL warrants contain cashless exercise provisions, and the other economic terms are comparable to those of the Preferred Stock, except that there is no liquidation preference associated with the Series LL warrants or shares issuable on the exercise thereof. The Securities Exchange Agreement also contains certain provisions that prohibit the payment of dividends, distributions of common stock or issuances of common stock at effective prices less than $1.35. There was no other consideration paid or received for the exchange. No gain or loss was recognized in our consolidated financial statements as a result of the exchange. The exchange transaction was entered into in connection with the filing of an application to list the Company’s common stock on the Tel Aviv Stock Exchange (TASE) in order to comply with a listing requirement of the TASE requiring that listed companies have only one class of equity securities issued and outstanding. Following the exchange, the Company has no shares of preferred stock outstanding.

In September 2015, we issued four-year Series MM warrants to purchase 150,000 shares of our common stock at an exercise price of $2.50 per share pursuant to an advisory services agreement with Chardan Capital Markets, LLC

(Chardan). Warrants to purchase an additional 150,000 shares of our common stock on the same terms are issuable to Chardan if they meet certain performance goals as outlined in the agreement. The fair value of the warrants issued and issuable to Chardan of $256,000 was recorded as a non-cash selling, general and administrative expense during the three-month period ended September 30, 2015.

At September 30, 2015, there are 16.6 million warrants outstanding to purchase Navidea's common stock. The warrants are exercisable at prices ranging from $0.01 to $3.04 per share with a weighted average exercise price of $0.25 per share. The warrants have remaining outstanding terms ranging from 0 to 20 years.

In addition, at September 30, 2015, there are 300 warrants outstanding to purchase MT Common Stock. The warrants are exercisable at $2,000 per share.

11. Reduction in Force

In March 2015, the Company initiated a reduction in force that included seven staff members and three executives. The executives continued as employees during transition periods of varying lengths, depending upon the nature and extent of responsibilities transitioned or wound down.

During the nine-month period ended September 30, 2015, the Company recognized approximately $1.3 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 $273,000.

A summary of changes in accrued separation costs during the nine-month period ended September 30, 2015 is presented below:

Accrued separation costs, December 31, 2014	$449,351
Payments related to May 2014 reduction in force	(409,947)
Charges incurred with March 2015 reduction in force	994,572
Payments related to March 2015 reduction in force	(994,572)
Accrued separation costs, September 30, 2015	$39,404

The remaining accrued separation costs related to the Company's reductions in force represent the estimated cost of continuing healthcare coverage, and are included in accrued liabilities and other on the consolidated balance sheet as of September 30, 2015.

12. Termination of Sublicense

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.

13. Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases, and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. Due to the uncertainty surrounding the realization of the deferred tax assets in future tax returns, all of the deferred tax assets have been fully offset by a valuation allowance at September 30, 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 the ultimate deductibility of all tax positions is highly certain, although there is uncertainty about the timing of such deductibility. As a result, no liability for uncertain tax positions was recorded as of September 30, 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 September 30, 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 other diagnostic applications of our Manocept platform, our R-NAV subsidiary, NAV4694 and NAV5001, and (ii) therapeutic

development programs, including therapeutic applications of our Manocept platform and all development programs undertaken by Macrophage Therapeutics, Inc.

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

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

Nine Months Ended September 30, 2015	Diagnostics	Therapeutics	Corporate	Total
Lymphoseek sales revenue:				
United States[1]	$6,736,418	$ —	$—	$6,736,418
International	15,074	—	—	15,074
Lymphoseek license revenue	883,333	—	—	883,333
Grant and other revenue	1,320,816	—	—	1,320,816
Total revenue	8,955,641	—	—	8,955,641
Cost of goods sold, excluding depreciation and amortization	1,167,141	—	—	1,167,141
Research and development expenses, excluding depreciation and amortization	9,610,012	559,888	—	10,169,900
Selling, general and administrative expenses, excluding depreciation and amortization[2]	4,634,279	120,872	8,381,910	13,137,061
Depreciation and amortization[3]	207,498	—	223,870	431,368

Loss from operations[4]	(6,663,289)	(680,760)	(8,605,780)	(15,949,829)
Other income (expense), excluding equity in the loss of R-NAV, LLC[5]	—	—	(8,808,202)	(8,808,202)
Equity in the loss of R-NAV, LLC	—	—	(295,217)	(295,217)
Net loss	(6,663,289)	(680,760)	(17,709,199)	(25,053,248)
Total assets, net of depreciation and amortization:				
United States	3,750,702	—	13,291,939	17,042,641
International	440,349	—	467	440,816
Capital expenditures	25,492	—	4,914	30,406

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

[2] General and administrative expenses, excluding depreciation and amortization, represent costs that relate to the general administration of the Company and as such are not currently allocated to our individual reportable segments. Marketing and selling expenses are allocated to our individual reportable segments.

[3] Depreciation and amortization is reflected in cost of goods sold ($15,496 and $72,237 for the three and nine months ended September 30, 2015), research and development ($1,517 and $10,617 for the three and nine months ended September 30, 2015), and selling, general and administrative expenses ($115,216 and $348,514 for the three and nine months ended September 30, 2015).

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

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

15. Supplemental Disclosure for Statements of Cash Flows

During the nine-month periods ended September 30, 2015 and 2014, we paid interest aggregating $3.3 million and $2.1 million, respectively. During the nine-month periods ended September 30, 2015 and 2014, we recorded $1.0 million and $2.4 million, respectively, of end-of-term fees associated with our notes payable to CRG and Oxford.

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.

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 to specifically target the CD206 mannose receptor expressed on activated macrophages. The Manocept platform serves as the molecular backbone of Lymphoseek® (technetium Tc 99m tilmanocept) injection, the first product developed 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 a therapeutic agent also suggest that tilmanocept's binding affinity to CD206 receptors demonstrates the potential for this technology to be useful in treating diseases linked to the over-activation of macrophages. This includes various cancers as well as autoimmune, infectious, cardiovascular, and central nervous system diseases. Thus, in January 2015, the Company formed a new subsidiary, Macrophage Therapeutics, Inc., to further explore therapeutic applications for the Manocept platform.

In addition, the Company's Board of Directors made the decision last year to reduce our support for, while seeking to partner or out-license, two of our neurological 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 discussions related to the potential partnering or divestiture of 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. In April 2015, the Company entered into an agreement with Alseres to terminate the NAV5001 sub-license agreement. The Company is currently engaged in discussions related to the potential partnering or divestiture of NAV4694.

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

The Company 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, the formation of Macrophage Therapeutics, Inc. in January 2015, and Macrophage Therapeutics' research collaboration agreement with BIND Therapeutics executed in June 2015, which we believe may further expand the Company's pipeline but which require less near-term funding from Navidea than the 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 trials in anal/rectal, endometrial, and cervical cancers, and others in various stages of execution, planning or consideration, are anticipated to provide additional data to potentially support 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

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) + VBD 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).

In June 2015, results of an investigator-initiated, comparative study of Lymphoseek versus filtered Tc-99m Sulfur Colloid (fTcSC) measuring injection site pain in patients with breast cancer undergoing lymphoscintigraphy were presented at the 2015 Society of Nuclear Medicine and Molecular Imaging (SNMMI) conference. The results of the trial, led by Anne Wallace, M.D., professor of surgery at University of California, San Diego (UCSD) School of Medicine, highlighted that fTcSC caused statistically significant greater levels of pain after injection compared to Lymphoseek. The randomized, double-blind clinical trial compared post-injection site pain using fTcSC versus

Lymphoseek in 52 [(27) fTcSC and (25) Lymphoseek] breast cancer patients undergoing lymphoscintigraphy. Pain was evaluated with a visual analogue scale and short form McGill Pain Questionnaire at 1, 2, 3, 4, 5, 15 and 30 minutes post-injection. Analysis of the data indicates baseline pain scores were similar between groups. At one minute post-injection, patients receiving fTcSC experienced a mean change in pain of 16.8mm (standard deviation (SD) 19.5) compared to 0.2mm (SD 7.3) in the Lymphoseek group (p =0.0002). Overall, patients receiving Lymphoseek experienced statistically significant less change in pain scores compared to patients receiving fTcSC at 1-3 minutes post-injection.

In July 2015, we announced the peer-reviewed publication of data verifying the Lymphoseek CD206-binding mechanism of action in the Journal of Immunology. Strong evidence-based studies demonstrate macrophages are the major target cell and identify CD206, the mannose receptor, as the tilmanocept-binding receptor. CD206 is highly expressed on the surface of tissue macrophages that are known to reside in the sentinel lymph nodes (SLNs) draining a primary tumor.

In August 2015, we announced the publication of the results from an investigator-initiated, comparative study of Lymphoseek versus filtered Tc-99m Sulfur Colloid (fTcSC) measuring injection site pain in patients with breast cancer undergoing lymphoscintigraphy. The paper, titled “Comparison of Post-injection Site Pain Between Technetium Sulfur Colloid and Technetium Tilmanocept in Breast

Cancer Patients Undergoing Sentinel Lymph Node Biopsy," was published online in the Annals of Surgical Oncology and indicated, with patient-reported data, a statistically significant reduction in the level of post-injection associated pain using Lymphoseek compared with use of an fTcSC tracer. The publication included results of the randomized, double-blind clinical trial comparing post-injection site pain using fTcSC versus Lymphoseek in 52 [(27) fTcSC and (25) Lymphoseek] breast cancer patients undergoing lymphoscintigraphy. Pain was evaluated with a visual analogue scale and short form McGill Pain Questionnaire at 1, 2, 3, 4, 5, 15 and 30 minutes post-injection. Analysis of the data indicated baseline pain scores were similar between groups. At one minute post-injection, patients receiving fTcSC experienced a mean change in pain of 16.8mm (standard deviation (SD) 19.5) compared to 0.2mm (SD 7.3) in the Lymphoseek group (p =0.0002). Overall, patients receiving Lymphoseek experienced statistically significant less change in pain scores compared to patients receiving fTcSC at 1-3 minutes post-injection.

Manocept Platform - Diagnostics and Therapeutics Background

Navidea's Manocept platform is predicated on the ability to specifically target the CD206 mannose receptor expressed on activated macrophages. Activated macrophages play important roles in many disease states and are an emerging target in many diseases where diagnostic uncertainty exists. This flexible and versatile platform serves as an engine for purpose-built molecules that may enhance diagnostic accuracy, clinical decision-making, targeted treatment 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 erythematosis, Kaposi's sarcoma (KS), and others that span clinical areas in oncology, autoimmunity, infectious diseases, cardiology, central nervous system (CNS) diseases, and inflammation. Data from studies using agents from the Manocept platform in RA, KS and TB were published in a special supplement, Nature Outlook: Medical Imaging, in Nature's October 31, 2013 issue. The supplement included a White Paper by Navidea entitled "Innovations in receptor-targeted precision imaging at Navidea: Diagnosis up close and personal," focused on the Manocept platform.

Manocept Platform - Diagnostics Clinical Data

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

In July 2015, imaging results from the Manocept clinical trial in KS and other preclinical studies were presented at the 18th International Workshop on Kaposi's Sarcoma Herpesvirus (KSHV) and Related Agents. The clinical imaging study, using Tc 99m tilmanocept in both HIV+ and HIV- patients suggests that KS tumor lesions, both cutaneous and suspected extra-cutaneous sites, can be easily visualized and mapped, demonstrating that this technique may potentially provide a means for routine patient assessment. The results also show that use of Manocept represents a potential therapeutic pathway for targeting tumor-associated macrophages (TAMs). Manocept agents are designed to target CD206, which is highly expressed on TAMs and the KS tumor itself. As a potential therapeutic, Manocept could be used as a precision vehicle to deliver payloads to tumor sites throughout the body. Five Human Herpes Virus8 positive (HHV8+) patients (4 HIV+, 1HIV-) were enrolled in the NAV3-12 study. Patients received a single subcutaneous injection of Tc 99m tilmanocept in the region of a cutaneous KS lesion and imaging was performed at 1, 4 and 24 hours post-injection to visualize localization of tilmanocept. Results represented by whole body SPECT/CT imaging scans from study patients were presented. Collectively, the scans show localization of tilmanocept and detected multiple cutaneous lesions in the extremities, face and genitalia, as well as extra-cutaneous localization found in the nasopharynx, lymph nodes and brain. Results also indicate that KS lesions are anatomically linked in chains by and within the lymph ducts. The study concludes that both HIV+ and

HIV- patients have pan-tumor expression of CD206, strongly suggests tilmanocept crosses the blood-brain barrier and that a Manocept-drug conjugate may have the potential as a therapeutic with high target effect and low off-target concerns. The data from these studies also suggest a novel theory on the genesis of KS in which KS arises from an HHV8 infected macrophage type cell and its interaction with the lymphatic system. This interaction provides the means for access of the KS through CD206 receptor for diagnosis, evaluation, and potential therapy using the Manocept platform.

In July 2015, we received a notice of award for a Phase 1 Small Business Innovation Research (SBIR) grant providing $322,000 from the National Heart Lung and Blood Institute (NHLBI), National Institutes of Health (NIH). The study, expected to be done in collaboration with Massachusetts General Hospital (MGH) and Harvard Medical School, will examine the ability of Tc 99m tilmanocept to localize in high-risk atherosclerotic plaques. These specific plaques are rich in CD206 expressing macrophages and are at high risk for near term rupture resulting in myocardial infarctions, sudden cardiac death and strokes. The consequences of atherosclerosis and the cardiovascular disease (CVD) that atherosclerosis causes, while severe in all populations of people, are particularly concentrated in HIV+ patients. Recently, it has been observed that CD206 expressing macrophages densely populate vulnerable plaques or thin cap fibroatheromas (TCFA) but not other kinds (i.e., stable) of atherosclerotic plaques. A primary goal for this grant involves an approved clinical investigation of up to 18 individuals with and without aortic and high risk coronary atherosclerotic plaques and with and without HIV infection to determine the feasibility of Tc 99m tilmanocept to image high risk plaque by SPECT/CT. Results have the potential to provide evidence of the potential of Tc 99m tilmanocept to accumulate in high risk morphology plaques, the ability to make preliminary comparisons of aortic Tc 99m tilmanocept uptake by SPECT/CT in each group, and to evaluate the ability of Tc 99m tilmanocept to identify the same aortic atherosclerotic plaques that are identified by contrast enhanced coronary computed tomography angiography (CCTA) and/or PET/CT.

Also in July 2015, we received an initial notice of award for a Fast Track SBIR grant providing for up to $1.7 million from the NIH's National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMD), to fund preclinical animal studies and a Phase 1/2 human clinical study examining the ability of Tc 99m tilmanocept to identify skeletal joints that are inflamed due to RA. RA is a chronic, progressive, systemic autoimmune disease characterized by inflammation of numerous skeletal joints. If not treated successfully, RA can lead to disability, disfigurement and premature death. The funds for this Fast Track grant will be released in two parts, which together have the potential to provide a total of $1.7 million in resources over two and a half years to achieve the specific aims and objectives of the grant. The first part will provide $225,000 to support preclinical animal studies and to support activities needed to prepare for the Phase 1/2 clinical study. The second part of the award will support the Phase 1/2 study, the results from which are expected to confirm the safety and effectiveness of Tc 99m tilmanocept to identify skeletal joint inflammation due to RA.

In September 2015, we received an initial notice of award for a Fast Track SBIR grant providing for up to $1.8 million from the NIH’s National Cancer Institute (NCI) to fund preclinical studies examining the safety of intravenous (IV) injection of Tc99m tilmanocept, a Manocept platform product, followed by a clinical study providing the initial evaluation of the safety and efficacy of SPECT imaging studies with IV Tc99m tilmanocept to identify and quantify both skin- and organ-associated KS lesions in human patients. The grant is awarded in two parts with the potential for total grant money of up to $1.8 million over two and a half years. The first six-month funding segment of $300,000, which has already been awarded, is expected to enable Navidea to secure necessary collaborations and Institutional Review Board approvals. The second funding segment could provide for up to an additional $1.5 million to be used to accrue participants, perform the Phase 1/2 study and perform data analyses to confirm the safety and effectiveness of intravenously administered Tc99m tilmanocept.

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® (radioimmunguided surgery) program. NAV1800 was originally intended to use a monoclonal antibody as an aid in identifying TAG-72, a specific factor associated with a primary tumor, ascertaining tumor margins, or determining the extent and location of occult and metastatic tumor in

patients with solid tumor cancers, such as colorectal cancer, ovarian cancer, or endometrial cancer. The detection of clinically occult tumor 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 NAV1800 program have 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. A key part of our ongoing consideration of the NAV1800 program involved an evaluation of the manufacturability of the humanized monoclonal antibody known as CC49, and ultimately the clinical and commercial viability. In recent years, these evaluations and new clinical data have caused us to question the viability of the monoclonal antibody initiative as it was originally envisioned. During the same time period, we learned significantly more about tilmanocept, the underlying Manocept backbone, and the potential utility of tilmanocept in identifying TAMs, and their consequent potential utility in identifying multifocal tumor disease itself. To that end, we petitioned the NIH to repurpose the grant we were previously awarded towards the study of TAMs in colorectal cancer, and subsequently received confirmation of the acceptance of this repurposing. We anticipate this repurposed grant will now support a diagnostic approach in patients with anal/rectal cancer and possibly colon cancer. We recognize this repurposing represents a major refocusing of the original NAV1800 initiative, but we are

confident that this change represents the best course of action at this time towards benefiting patients afflicted with colorectal cancer and is one which is consistent with the excitement we are seeing on many fronts related to our work on the Manocept platform. However, we cannot assure you that if further clinical trials for this product proceed, that they will be successful, that the product will achieve regulatory approval, or if approved, that it will achieve market acceptance.

Macrophage Therapeutics Background

In 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 (collectively, the Investors) 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 the 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 that may 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 June 2015, BIND Therapeutics, Inc. (BIND), a clinical-stage nanomedicine company developing targeted and programmable therapeutics called Accurins™, and MT entered into a research collaboration to engineer Accurins with the Manocept targeting platform. Disease-associated macrophages generally play a pro-tumoral role and are immunosuppressive, preventing the immune system from mounting an attack on tumor cells. Based on the expression of CD206 mannose receptors on disease-associated macrophages, BIND and MT plan to conduct joint research to develop a CD206 targeted Accurin nanoparticle that is capable of concentrating various therapeutic payloads to the tumor microenvironment.

In September 2015, MT announced that it had developed a process for producing the first two therapeutic Manocept immunoconstructs, MT-1001, designed to specifically target and kill activated CD206+ macrophages and MT-2001, designed to inhibit the inflammatory activity of activated CD206+ macrophages. Activated CD206+ macrophages are implicated in numerous diseases ranging from cancer to autoimmune diseases to CNS diseases like Alzheimer's disease and multiple sclerosis. MT-1001 and MT-2001 were developed from the Manocept platform technology and contain a similar chemical scaffold and targeting moieties designed to selectively target CD206+ macrophages. A payload of a therapeutic molecule is conjugated to each immunoconstruct through a linkage that will release the molecule within the targeted tissue: MT-1001 has doxorubicin, an anthracycline antitumor antibiotic, conjugated to the Manocept backbone and MT-2001 has a potent anti-inflammatory agent conjugated to it. Macrophage Therapeutics has contracted with an independent facility to produce sufficient quantities of MT-1001 and MT-2001 along with the concomitant analytical standards, to provide material for planned preclinical animal studies.

Manocept Platform - Therapeutics Clinical Data

In March 2015, MT announced that data from an ongoing human study indicated 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 these data and on the advice of the Company's SAB, MT will expand the SAB to include members with specific expertise in CNS diseases. The blood brain barrier has proven to be a significant obstacle to treating many diseases of the central nervous system. In an imaging study using the Manocept targeted delivery system, foci on the other side of the blood brain barrier were observed that strongly and specifically localized tilmanocept. Many of the leading diseases of the central nervous system such as Alzheimer's and Parkinson's diseases as well as autoimmune CNS diseases such as multiple sclerosis and ALS have pathologies that can in part be attributed to over-active macrophages, the target for Manocept delivery technology.

In 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.

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

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

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 discussions related to the potential partnering or divestiture of 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. In October 2014, we received approval from FDA for a significantly expanded product label for Lymphoseek. During the second quarter of 2015, we successfully deployed Navidea's direct sales personnel as part of our effort to accelerate Lymphoseek revenue growth in the remainder of 2015 and beyond. Our strategy for increasing Lymphoseek revenue focuses on a new brand strategy reflective of the 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 $10.2 million and $14.5 million in total on research and development activities during the nine-month periods ended September 30, 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:

	Nine Months Ended
	September 30,

Development Program	2015	2014
Lymphoseek	$1,581,037	$1,669,421
Manocept Platform	683,298	453,311
Macrophage Therapeutics	418,633	—
NAV4694	3,092,864	5,414,838
NAV5001	194,153	1,198,313
NAV1800	—	34,393

We expect to continue the advancement of our efforts with Lymphoseek and our Manocept platform during the remainder of 2015. The divestiture of NAV5001 and the temporary suspension of active patient accrual in our NAV4694 trials has decreased our development costs year-to-date, however, we continue to incur costs to maintain the trials and drug production while we complete our partnering activities. We continue to expect that our total research and development expenses for 2015 will be lower than 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 included seven staff members and three executives. The executives continued as employees during transition periods of varying lengths, depending upon the nature and extent of responsibilities transitioned or wound down. During the nine-month period ended September 30, 2015, the Company recognized approximately $1.3 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 continue to remain at approximately 80% in the coming quarters. During 2015, we have continued making limited investment in the NAV4694 clinical trial process based on our expectation that we will be successful in ultimately securing a partnership that will provide us some level of return on this investment. The Company also expects that, following completion of partnering or divestiture of NAV4694, cash operating expenses on a quarterly basis will continue to decrease, excluding therapeutic-related research and development costs for the Manocept platform.

Results of Operations

Three Months Ended September 30, 2015 and 2014

Lymphoseek Sales and Margins. Net sales of Lymphoseek were $3.0 million during the third quarter of 2015, compared to $1.1 million during the same period of 2014. The increase was primarily the result of continued efforts to increase sales. Gross margins on net sales were 85% and 27% for the third quarters of 2015 and 2014, respectively. Cost of goods sold in the third quarter of 2015 included a net benefit of $173,000 related to our ability to sell certain previously reserved inventory, partially offset by reserves for inventory obsolescence totaling $48,000 related to specific lots which are nearing product expiry and therefore are no longer expected to be sold. Cost of goods sold in the third quarter of 2014 included a reserve for inventory obsolescence of $539,000 related to a specific lot which was originally produced for validation purposes but was nearing its product expiry and therefore was no longer expected to be sold. Cost of goods sold in both periods included post-production testing activities required by regulatory authorities, which are charged as one-time period costs, and a royalty on net sales payable under our license agreement with UCSD.

Lymphoseek License Revenue. During the third quarters of 2015 and 2014, we recognized $300,000 of Lymphoseek milestone revenue from non-refundable milestone payments received by the Company related to the Lymphoseek distribution agreement for China, for which the Company has no future obligations. During the third quarter of 2015, we also recognized $250,000 of the $2.0 million non-refundable upfront payment received by the Company related to the Lymphoseek license and distribution agreement for Europe, which the Company is recognizing on a straight-line basis over two years.

Grant and Other Revenue. During the third quarter of 2015, we recognized $477,000 of grant and other revenue as compared to $849,000 in the third quarter of 2014. Grant revenue during the third quarter of 2015 was primarily related to SBIR grants from the NIH supporting NAV4694, coupled with grants for the development of certain aspects of Manocept platform and Lymphoseek. Grant

revenue during the third quarter of 2014 was primarily from two SBIR grants from the NIH supporting NAV4694. Grant and other revenue for the third quarters of 2015 and 2014 also included $42,000 and $47,000, respectively, of revenue related to services provided to R-NAV for Manocept development.

Research and Development Expenses. Research and development expenses decreased $256,000, or 6%, to $3.9 million during the third quarter of 2015 from $4.2 million during the same period in 2014. The net decrease was primarily due to decreased compensation including incentive-based awards and other expenses related to net decreased headcount of $258,000 following the first quarter 2015 and third quarter 2014 reductions in force coupled with decreased travel, office and other support costs of $60,000. These decreases were partially offset by net increases in drug project expenses related to (i) increased therapeutics development costs of $237,000 including increased manufacturing-related activities and scientific advisory board fees; (ii) increased Manocept development costs of $216,000 including increased clinical trial costs, license fees and manufacturing-related activities, offset by decreased preclinical testing; and (iii) increased Lymphoseek development costs of $63,000 including increased preclinical testing, clinical trial costs, and life cycle management, offset by decreased manufacturing-related activities, European regulatory costs, and license fees; offset by (iv) decreased NAV5001 development costs of $243,000 including decreased clinical trial costs and manufacturing-related activities; and (v) decreased NAV4694 development costs of $207,000 including decreased manufacturing-related activities and license fees offset by increased clinical trial costs related to keeping the trials open while partnering efforts are ongoing.

Selling, General and Administrative Expenses. Selling, general and administrative expenses increased $1.3 million, or 49%, to $3.9 million during the third quarter of 2015 from $2.6 million during the same period in 2014. The net increase was primarily due to increased commercial and medical headcount coupled with increased legal and professional services, offset by decreased costs for contracted medical science liaisons, decreased professional services and market development expenses related to Lymphoseek, decreased recruiting related to the search for a new CEO in 2014, and decreased board compensation including stock-based awards. Selling, general and administrative expenses were also impacted by the reductions in force during 2014 and 2015.

Other Income (Expense). Other expense, net, was $3.7 million during the third quarter of 2015 as compared to other expense, net of $1.5 million during the same period in 2014. Interest expense, net increased $1.2 million to $2.1 million during the third quarter of 2015 from $918,000 for the same period in 2014, primarily due to the higher outstanding balances and higher interest rates related to the CRG Term Loan in 2015 versus the Oxford Notes in 2014, coupled with the higher outstanding balances and higher interest rates related to the Platinum Note in 2015 versus 2014. Of this interest expense, $65,000 and $201,000 in the third 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 CRG Term Loan and Oxford Notes. An additional $802,000 of this interest expense was compounded and added to the balance of our notes payable during the third quarter of 2015. For the third quarters of 2015 and 2014, we recorded non-cash expenses of $1.6 million and $410,000, respectively, related to changes in the estimated fair value of financial instruments. During the third quarters of 2015 and 2014, we recorded non-cash equity in the loss of R-NAV of $27,000 and $262,000, respectively.

Nine Months Ended September 30, 2015 and 2014

Lymphoseek Sales and Margins. Net sales of Lymphoseek were $6.8 million during the first nine months of 2015, compared to $2.8 million during the same period of 2014. The increase was primarily the result of continued efforts to increase sales. Gross margins on net sales were 82% and 54% for the first nine months of 2015 and 2014, respectively. Cost of goods sold in the first nine months of 2015 included a net benefit of $247,000 related to our ability to sell certain previously reserved inventory, partially offset by net inventory losses of $93,000 related to a production matter and reserves for inventory obsolescence totaling $48,000 related to specific lots which are nearing product expiry and therefore are no longer expected to be sold. Cost of goods sold in the first nine months of 2014 included a reserve for inventory obsolescence of $539,000 related to a specific lot which was originally produced for validation purposes but was nearing its product expiry and therefore was no longer expected to be sold. Cost of goods

sold in both periods included post-production testing activities required by regulatory authorities, which are charged as one-time period costs, and a royalty on net sales payable under our license agreement with UCSD.

Lymphoseek License Revenue. During the first nine months of 2015, we recognized $583,000 of the $2.0 million non-refundable upfront payment received by the Company related to the Lymphoseek license and distribution agreement for Europe, which the Company is recognizing on a straight-line basis over two years. During the first nine months of 2015 and 2014, we recognized $300,000 of Lymphoseek milestone revenue from non-refundable milestone payments received by the Company related to the Lymphoseek distribution agreement for China, for which the Company has no future obligations.

Grant and Other Revenue. During the first nine months of 2015, we recognized $1.3 million of grant and other revenue as compared to $1.0 million in the first nine months of 2014. Grant revenue during the first nine months of 2015 was primarily related to SBIR grants from the NIH supporting NAV4694, Lymphoseek and Manocept platform development. Grant revenue during the first nine months of 2014 was primarily related to SBIR grants from the NIH supporting NAV4694 and NAV1800 development. Grant and other revenue for the first nine months of 2015 and 2015 also included $120,000 and $47,000, respectively, of revenue related to services provided to R-NAV for Manocept development.

Research and Development Expenses. Research and development expenses decreased $4.3 million, or 30%, to $10.2 million during the first nine months of 2015 from $14.5 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 $2.3 million including decreased clinical trial costs and manufacturing-related activities; (ii) decreased NAV5001 development costs of $1.0 million including decreased manufacturing-related activities and clinical trial costs; and (iii) decreased Lymphoseek development costs of $88,000 including decreased European regulatory costs offset by increased preclinical testing, manufacturing-related activities and clinical trial costs; offset by (iv) increased therapeutics development costs of $419,000 including increased scientific advisory board fees and manufacturing-related activities; and (v) increased Manocept platform development costs of $230,000 including increased clinical trial costs, license fees and manufacturing-related activities, offset by decreased preclinical testing. The net decrease in research and development expenses also included decreased compensation including incentive-based awards and other expenses related to net decreased headcount of $830,000 following the first quarter 2015 and second quarter 2014 reductions in force coupled with decreased travel, office and other support costs of $685,000.

Selling, General and Administrative Expenses. Selling, general and administrative expenses increased $2.0 million, or 18%, to $13.5 million during the first nine months of 2015 from $11.5 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 increased internal commercial and medical education headcount coupled with costs related to the first quarter 2015 reduction in force. The net increase in selling, general and administrative expenses also included increased legal and professional services, license fees related to Lymphoseek, market development expenses related to NAV4694, investor relations costs, and travel, office and other support costs, offset by decreased costs for contracted medical science liaisons and decreased professional services and market development expenses related to Lymphoseek.

Other Income (Expense). Other expense, net, was $9.1 million during the first nine months of 2015 as compared to other expense, net of $5.7 million during the same period in 2014. Interest expense, net increased $1.9 million to $4.7 million during the first nine months of 2015 from $2.8 million for the same period in 2014, primarily due to the higher outstanding balances and higher interest rates related to the CRG Term Loan and Oxford Notes in 2015 versus the Oxford Notes and GECC/MidCap Notes in 2014, coupled with the higher outstanding balances and higher interest rates of the Platinum Note in 2015 compared to 2014. Of this interest expense, $424,000 and $638,000 in the first nine months of 2015 and 2014, respectively, was non-cash in nature related to the amortization of debt discounts related to the CRG Term Loan, Oxford Notes and GECC/MidCap Notes. An additional $1.2 million of this interest expense was compounded and added to the balance of our notes payable during the first nine months of 2015. During the first nine months of 2015 and 2014, we recorded $2.4 million and $2.6 million, respectively, of losses on the extinguishment of the Oxford Notes and GECC/MidCap Notes. For the first nine months of 2015 and 2014, we recorded non-cash expenses of $1.7 million and $109,000, respectively, related to changes in the estimated fair value of financial instruments. During the first nine months of 2015 and 2014, we recorded non-cash equity in the loss of R-NAV of $295,000 and $262,000, respectively.

Liquidity and Capital Resources

Cash balances increased to $11.4 million at September 30, 2015 from $5.5 million at December 31, 2014. The net increase was primarily due to cash received from the CRG Term Loan of $50.0 million, draws under the Platinum

credit facility of $4.5 million and the issuance of MT Preferred Stock of $500,000, offset by principal payments on the Oxford Notes of $30.0 million, cash used to fund our operations of $14.9 million, and payment of debt-related costs of $3.9 million.

Operating Activities. Cash used in operations decreased $9.4 million to $14.9 million during the first nine months of 2015 compared to $24.3 million used during the same period in 2014.

Accounts receivable increased to $1.9 million at September 30, 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 $877,000 at September 30, 2015 from $932,000 at December 31, 2014, primarily due to finished goods inventory sold and materials inventory consumed for process development, offset by materials and finished goods inventory produced. We expect inventory levels to increase modestly over the remainder of 2015 as we produce additional Lymphoseek inventory to meet increasing demand.

Prepaid expenses and other current assets decreased to $808,000 at September 30, 2015 from $1.4 million at December 31, 2014, primarily due to amortization of prepaid insurance coupled with application of a prepaid deposit to a new lot of materials inventory.

Accounts payable decreased to $1.3 million at September 30, 2015 from $1.5 million at December 31, 2014, primarily due to net decreased payables due to medical education, legal and professional services, commercial, and Lymphoseek vendors, offset by net increased payables due to NAV4694, and Manocept vendors. Accrued liabilities and other current liabilities increased to $3.6 million at September 30, 2015 from $3.2 million at December 31, 2014, primarily due to increased accruals for NAV4694 development costs, legal and professional services, accrued interest, and Manocept development costs, offset by decreased accruals for Lymphoseek development costs, NAV5001 development costs, compensation-related costs, and marketing and medical education costs. Our payable and accrual balances will continue to fluctuate but will likely decrease overall as we continue to decrease our level of development activity related to NAV4694, offset by planned increases in commercial activity related to Lymphoseek and development activity related to the Manocept platform.

Investing Activities. Investing activities used $19,000 during the first nine months of 2015 compared to using $1.5 million during the same period in 2014. Capital expenditures of $30,000 during the first nine months of 2015 were primarily for Lymphoseek production equipment. Proceeds from sales of equipment of $38,000 were offset by patent and trademark costs of $27,000 during the first nine months of 2015. Capital expenditures of $1.1 million during the first nine months of 2014 were primarily for leasehold improvements, office furniture and NAV4694 production equipment. Investing activities in the first nine months of 2014 also included investment in R-NAV of $333,000 and patent and trademark costs of $52,000. 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 $20.8 million during the first nine months of 2015 compared to $3.2 million provided during the same period in 2014. The $20.8 million provided by financing activities in the first nine months of 2015 consisted primarily of proceeds from the CRG Term Loan of $50.0 million, draws under the Platinum credit facility of $4.5 million, and proceeds from issuance of MT Preferred Stock of $500,000, offset by principal payments on the Oxford Notes of $30.0 million, payment of debt-related costs of $3.9 million, and principal payment on the R-NAV note of $333,000. The $3.2 million provided by financing activities in the first nine months of 2014 consisted primarily of proceeds from the Oxford Notes of $30.0 million, offset by principal payments on the GECC/MidCap Notes of $25.0 million and payment of debt-related costs of $1.8 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 (collectively, the Investors) 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 that may be sold under the agreement are convertible into and exercisable for MT Common Stock would represent 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 the 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 $295,000 for the nine-month period ended September 30, 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 $54,000 of in-kind services during the nine-month period ended September 30, 2015. As of September 30, 2015, the Company has $408,000 of in-kind services remaining to provide under this obligation. A principal payment of $333,333 was made on the note payable to R-NAV in July 2015. As of September 30, 2015, the outstanding principal balance of the note payable to R-NAV was $333,333. The final payment of $333,333 is due in July 2016.

Capital Royalty Group Debt

In May 2015, Navidea and its subsidiary Macrophage Therapeutics, Inc., as guarantor, executed a Term Loan Agreement (the CRG Loan Agreement) with Capital Royalty Partners II L.P. in its capacity as a lender and as control agent for other affiliated lenders party to the CRG Loan Agreement (collectively, the Lenders) in which the Lenders agreed to make a term loan to the Company in the aggregate principal amount of $50 million (the CRG Term Loan), with an additional $10 million in loans to be made available upon the satisfaction of certain conditions stated in the CRG Loan Agreement. Closing and funding of the CRG Term Loan occurred on May 15, 2015 (the Effective Date). The principal balance of the CRG Term Loan will bear interest from the Effective Date at a per annum rate of interest equal to 14.0%. Through March 31, 2019, the Company has the option of paying (i) 10.00% of the per annum interest in cash and (ii) 4.00% of the per annum interest as compounded interest, added to the aggregate principal amount of the CRG Term Loan. During the nine-month period ended September 30, 2015, $769,000 of interest was compounded and added to the balance of the CRG Term Loan. In addition, the Company began paying the cash portion of the interest in arrears on June 30, 2015. Principal is due in eight equal quarterly installments during the final two years of the term. All unpaid principal, and accrued and unpaid interest, is due and payable in full on March 31, 2021. As of September 30, 2015, the outstanding principal balance of the CRG Term Loan was $50.8 million, and we were in compliance with all covenants of the CRG Loan Agreement. The Company believes it is still possible to achieve the level of operational performance required to maintain compliance with the applicable covenants, but that if necessary, it has access to resources required to cure a potential shortfall. The majority of the proceeds from the CRG Note were used to repay all amounts outstanding under the Oxford Loan Agreement. The remaining proceeds are being 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 million, bearing interest at 8.5% (the Oxford Notes), and (2) Series KK warrants to purchase an aggregate of 391,032 shares of our common stock at an exercise price of $1.918 per share, expiring in March 2021 (the Series KK warrants). We began making monthly payments of interest only on April 1, 2014, and monthly payments of principal and interest beginning April 1, 2015. In May 2015, in connection with the consummation of the CRG Loan Agreement, the Company repaid all amounts outstanding under the Oxford Loan Agreement. The payoff amount of $31.6 million included payments of $289,000 as a pre-payment fee and $2.4 million as an end-of-term final payment fee.

Platinum Credit Facility

In May 2015, in connection with the execution of the CRG Loan Agreement, the Company amended the existing Platinum credit facility to allow this facility to remain in place in a subordinated role to the CRG Loan (the Third Platinum Amendment). Among other things, the Third Platinum Amendment (i) extends the term of the Platinum Loan Agreement until a date six months following the maturity date or earlier repayment of the CRG Term Loan; (ii) changes the interest rate to the greater of (a) the United States prime rate as reported in The Wall Street Journal plus 6.75%, (b) 10.0% and (c) the highest rate of interest then payable pursuant to the CRG Term Loan plus 0.125%; (iii) requires such interest to compound monthly; and (iv) changes the provisions of the Platinum Loan Agreement governing Platinum’s right to convert advances into common stock of the Company. The Third Platinum Amendment provides for the conversion of all principal and interest outstanding under the Platinum Loan Agreement, but not until such time as the average daily volume weighted average price of the Company’s common stock for the ten preceding trading days exceeds $2.53 per share. The amendment became effective upon initial funding of the CRG Loan Agreement.

The Platinum Loan Agreement, as amended, provides us with a credit facility of up to $50 million. The Company borrowed an additional $4.5 million under the Platinum Loan Agreement during the nine-month period ended

September 30, 2015. In addition, $462,000 of interest was compounded and added to the balance of the Third Amended Platinum Note during the nine-month period ended September 30, 2015. As of September 30, 2015, the outstanding principal balance of the Third Amended Platinum Note was approximately $8.2 million, consisting of $7.7 million of draws and $462,000 of compounded interest, with $27.3 million still 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 discussions related to the potential partnering or divestiture of NAV4694.

The Company is also working to establish additional sources of non-dilutive funding, including collaborations and grant funding that can augment the balance sheet as the Company works to reduce spending to levels that can be increasingly offset by growing Lymphoseek revenue. 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 Phase 3 neurological development programs. We plan to focus our resources for the remainder of 2015 and into 2016 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 the foundation with which to build our business. Our capital position is further supported by access to existing funding facilities, 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. We continually monitor our cash flows and financial projections with the goal of reaching cash flow breakeven from operations as soon as possible. At this time, we believe that meeting our previous guidance of achieving cash flow breakeven from operations during the first quarter of 2016 is still possible depending on the level of continued revenue growth we achieve over the next five months, the structure and timing of potential payments associated with ongoing asset divestiture discussions, and our ability to contain and/or significantly reduce our operating expenditures. During 2015, we have continued making limited investment in the NAV4694 clinical trial process based on our expectation that we will be successful in ultimately securing a partnership that will provide us some level of return on this investment which is incremental to the carrying costs we are presently incurring. However, we cannot assure you that Lymphoseek will generate our expected levels of sales and cash flow or that the partnership discussions in which we are engaged will yield the level of return we are anticipating. We will continue to evaluate our time lines, strategic needs, and balance sheet requirements. 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 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 Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2015-03, Simplifying the Presentation of Debt Issuance Costs. ASU 2015-03 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. During the second quarter of 2015, the Company elected early adoption of ASU 2015-03. The consolidated balance sheet as of December 31, 2014 has been adjusted to reflect retrospective application of the new method of presentation. Deferred debt issuance costs totaling $90,000 that were included in other assets as of December 31, 2014 were reclassified as discounts on notes payable, current, of $35,000 and discounts on notes payable, long term, of $55,000. We have reflected these costs as a reduction of the debt on the balance sheet as of September 30, 2015 and will continue to do so in future periods. The adoption of ASU 2015-03 had no impact on the consolidated statements of operations, stockholders' equity (deficit) or cash flows.

In July 2015, the FASB issued ASU No. 2015-11, Simplifying the Measurement of Inventory. ASU 2015-11 applies to all inventory that is measured using methods other than last-in, first-out or the retail inventory method, including inventory that is measured using first-in, first-out or average cost. ASU 2015-11 requires entities to measure inventory at the lower of cost and net realizable value, defined as the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. ASU 2015-11 is effective for public entities for fiscal years beginning after December 15, 2016, and interim periods with fiscal years beginning after December 15, 2017. The amendments in ASU 2015-11 should be applied prospectively with earlier application permitted as of the beginning of an interim or annual reporting period. We do not expect the adoption of ASU 2015-11 to have a material effect on our consolidated financial statements upon adoption.

In August 2015, the FASB issued ASU No. 2015-14, Revenue from Contracts with Customers. ASU 2015-14 defers the effective date of ASU No. 2014-09 for all entities by one year. Public business entities should adopt the new revenue recognition standard for annual reporting periods beginning after December 15, 2017, including interim periods within that year. Early adoption is permitted only as of annual reporting periods beginning after December 15, 2016, including interim periods within that year. We are evaluating the potential impact of the adoption of ASU 2014-09, but we do not currently expect the adoption 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. We generally recognize sales revenue related to sales of our products when the products are shipped. Our customers have no right to return products purchased in the ordinary course of business, however, we may allow returns in certain circumstances based on specific agreements.

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

these product sales at the minimum (i.e., floor) price provided for under our distribution agreement with Cardinal Health.

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

We generate additional revenue from grants to support various product development initiatives. We generally recognize grant revenue when expenses reimbursable under the grants have been paid and payments under the grants become contractually due. Lastly, we recognize revenues from the provision of services to R-NAV, 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 Financial Instruments. Certain of our notes payable are required to be recorded at fair value. The estimated fair value of our debt is calculated using a discounted cash flow analysis as well as a probability-weighted Monte Carlo simulation. These valuation methods include Level 3 inputs such as the estimated current market interest rate for similar instruments with similar creditworthiness. For the debt recorded at fair value, unrealized gains and losses on the fair value of the debt are classified in other expenses as a change in the fair value of financial instruments in the consolidated statements of operations.
- Fair Value of 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.

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Item 3. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk. As of September 30, 2015, our $11.4 million in cash was primarily invested in interest-bearing money market accounts. Due to the low interest rates being realized on these accounts, we believe that a hypothetical 10% increase or decrease in market interest rates would not have a material impact on our consolidated financial position, results of operations or cash flows.

We also have exposure to changes in interest rates on our variable-rate debt obligations. As of September 30, 2015, the interest rate on certain of our debt obligations was the greater of a stated rate or the U.S. prime rate plus 6.75%. Based on the effective rate of our variable-rate borrowings, which totaled approximately $8.2 million and were subject to the stated rate at September 30, 2015, an immediate one percentage point increase in the U.S. prime rate would not materially affect our annual interest expense. 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 stated 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 nine months ended September 30, 2015 and 2014, we recorded foreign currency transaction losses of approximately $32,000 and $49,000, 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 September 30, 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 September 30, 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 September 30, 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.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings

Section 16(b) Action

On August 12, 2015, a shareholder of the Company filed an action in the United States District Court for the Southern District of New York against two funds managed by Platinum Management (NY) LLC (Platinum) alleging violations of Section 16(b) of the Securities Exchange Act in connection with purchases and sales of the Company's common stock by the Platinum funds, and seeking disgorgement of the short-swing profits realized by the funds. The Company believes that the funds managed by Platinum own, of record or beneficially, more than five percent of the Company's outstanding common stock. The Company is a nominal defendant in the action, no relief is sought against the Company, and a portion of any amount awarded to the plaintiff by judgment or settlement of the action will likely accrue to the benefit of the Company.

Sinotau Litigation

On August 31, 2015, Sinotau Pharmaceutical Group (Sinotau) filed a suit for damages, specific performance and injunctive relief against the Company in the United States District Court for the District of Massachusetts alleging breach of a letter of intent for licensing to Sinotau of the Company's NAV4694 product candidate and technology. The Company believes the suit is without merit and has filed a motion to dismiss the action. While it is not possible to determine with any degree of certainty the ultimate outcome of this legal proceeding, including making a determination of liability, we believe that we have meritorious defenses with respect to the claims asserted against us and intend to vigorously defend our position.

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 (the Form 10-K), filed with the SEC on March 16, 2015, except for the following.

Our indebtedness imposes significant restrictions on us, and a default could materially adversely affect our operations and financial condition.

As described in Note 8 to the Financial Statements contained in Item 1 of Part I of this Report, and in Item 2 of Part 2 of this Report under the captions "Capital Royalty Group Debt" and "Oxford Debt," the loan from Oxford Finance, LLC referenced in this risk factor in the Form 10-K was repaid in full in May 2015 with proceeds from borrowings under the CRG Loan Agreement. The risks associated with the Oxford Debt described in the Form 10-K also apply to our indebtedness under the CRG Loan Agreement.

Platinum may exercise its conversion right, and that could dilute your ownership and the net tangible book value per share of our common stock.

As described in Note 8 to the Financial Statements contained in Item 1 of Part I of this Report, and in Item 2 of Part 2 of this Report under the caption "Platinum Credit Facility," in connection with the CRG Loan Agreement the Platinum

Loan Agreement referenced in this risk factor in the Form 10-K was amended. As part of the amendment, the conversion option was changed so that all advances under the Platinum Loan Agreement are now convertible at the option of Platinum. The amendment became effective upon initial funding of the CRG Loan Agreement and allows Platinum to convert the entire amount outstanding under the Platinum Loan Agreement (approximately $8.2 million at September 30, 2015) during any time period in which the Company's stock price exceeds $2.53 per share for 10 consecutive trading days. If Platinum exercises any or all of these conversion rights, the percentage ownership of our current stockholders will be reduced. The issuance of additional common stock may also result in dilution in the net tangible book value per share of our common stock.

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

During the three-month period ended September 30, 2015, we issued 35,637 shares of our common stock to certain members of our Board of Directors as payment of their second quarter 2015 retainers. The issuance of these securities was exempt from registration under Section 4(a)(2) of the Securities Act and Regulation D promulgated thereunder.

Also during the three-month period ended September 30, 2015, we issued four-year Series MM warrants to purchase 150,000 shares of our common stock at an exercise price of $2.50 per share pursuant to an advisory services agreement with Chardan Capital Markets, LLC. The issuance of these securities was exempt from registration under Section 4(a)(2) of the Securities Act and Regulation D promulgated thereunder.

Item 6. Exhibits

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

SIGNATURES

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

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

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**Furnished herewith.