NAVIDEA BIOPHARMACEUTICALS, INC.
Form 10-Q
November 10, 2014

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

FORM 10-Q
(Mark One)

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

For the quarterly period ended September 30, 2014

¨ 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 ¨

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 ¨

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 ¨ No x

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date: 150,740,481 shares of common stock, par value $.001 per share (as of the close of business on October 31, 2014).

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PART I – Financial Information

PART I – FINANCIAL INFORMATION

Item 1. Financial Statements

Navidea Biopharmaceuticals, Inc. and Subsidiaries
Consolidated Balance Sheets

ASSETS	September 30, 2014 (unaudited)	December 31, 2013
Current assets:		
Cash	$10,388,618	$32,939,026
Accounts receivable	1,465,426	1,150,626
Inventory	1,120,218	2,232,436
Prepaid expenses and other	1,003,466	1,009,094
Total current assets	13,977,728	37,331,182
Property and equipment	4,120,998	3,609,059
Less accumulated depreciation and amortization	1,477,501	1,483,676
	2,643,497	2,125,383
Patents and trademarks	194,250	163,302
Less accumulated amortization	36,063	26,448
	158,187	136,854
Investment in R-NAV, LLC	464,529	—
Other assets	397,977	723,098
Total assets	$17,641,918	$40,316,517

Continued

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

LIABILITIES AND STOCKHOLDERS' DEFICIT	September 30, 2014 (unaudited)	December 31, 2013
Current liabilities:		
Accounts payable	$2,376,939	$2,422,349
Accrued liabilities and other	3,231,696	4,772,963
Notes payable, current, net of discounts of $826,440 and $743,062, respectively	2,725,107	4,095,650
Total current liabilities	8,333,742	11,290,962
Notes payable, net of discounts of $1,731,010 and $856,746, respectively	29,756,627	23,572,603
Derivative liabilities	7,697,130	7,692,087
Other liabilities	3,116,188	1,770,452
Total liabilities	48,903,687	44,326,104
Commitments and contingencies		
Stockholders' deficit:		
Preferred stock; $.001 par value; 5,000,000 shares authorized; 3,143 and 7,565 Series B shares issued and outstanding at September 30, 2014 and December 31, 2013, respectively	3	8
Common stock; $.001 par value; 200,000,000 shares authorized; 150,735,382 and 135,919,423 shares issued and outstanding at September 30, 2014 and December 31, 2013, respectively	150,735	135,919
Additional paid-in capital	314,706,478	313,111,788
Accumulated deficit	(346,118,985)	(317,257,302)
Total stockholders' deficit	(31,261,769)	(4,009,587)
Total liabilities and stockholders' deficit	$17,641,918	$40,316,517

See accompanying notes to consolidated financial statements (unaudited).

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Revenue:				
Lymphoseek sales revenue	$1,101,071	$143,799	$2,773,959	$271,620
Lymphoseek milestone revenue	300,000	—	300,000	—
Grant and other revenue	848,999	256,575	1,002,605	324,031
Total revenue	2,250,070	400,374	4,076,564	595,651
Cost of goods sold	807,880	75,422	1,271,598	180,860
Gross profit	1,442,190	324,952	2,804,966	414,791
Operating expenses:				
Research and development	4,158,085	6,278,459	14,496,977	14,295,049
Selling, general and administrative	2,646,591	3,971,172	11,465,076	11,505,099
Total operating expenses	6,804,676	10,249,631	25,962,053	25,800,148
Loss from operations	(5,362,486)	(9,924,679)	(23,157,087)	(25,385,357)
Other income (expense):				
Interest income	2,879	5,623	14,691	9,082
Interest expense	(920,905)	(976,226)	(2,778,813)	(1,804,576)
Equity in loss of R-NAV, LLC	(262,198)	—	(262,198)	—
Change in fair value of financial instruments	(409,650)	(377,474)	(109,499)	(377,474)
Loss on extinguishment of debt	—	—	(2,610,196)	(1,372,266)
Other, net	53,464	(33,451)	41,419	(16,986)
Total other expense, net	(1,536,410)	(1,381,528)	(5,704,596)	(3,562,220)
Net loss attributable to common stockholders	$(6,898,896)	$(11,306,207)	$(28,861,683)	$(28,947,577)
Loss per common share (basic and diluted)	$(0.05)	$(0.09)	$(0.19)	$(0.25)
Weighted average shares outstanding (basic and diluted)	150,169,712	121,117,562	148,344,064	117,740,754

See accompanying notes to consolidated financial statements (unaudited).

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

	Preferred Stock		Common Stock		Additional Paid-In	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Deficit
Balance, December 31, 2013	7,565	$8	135,919,423	$135,919	$313,111,788	$(317,257,302)	$(4,009,587)
Issued stock upon exercise of stock options, net			241,314	241	(5,651)		(5,410)
Issued restricted stock			378,250	378	—		378
Canceled forfeited restricted stock	—	—	(300,000)	(300)	—	—	(300)
Issued stock to 401(k) plan	—	—	36,455	37	100,007	—	100,044
Conversion of Series B preferred stock to common stock	(4,422)	(5)	14,459,940	14,460	(14,455)		—
Issued warrants in connection with debt issuance					464,991		464,991
Recovery of shareholder short swing profits					17,554		17,554
Stock compensation expense					1,032,244		1,032,244
Net loss						(28,861,683)	(28,861,683)
Balance, September 30, 2014	3,143	$3	150,735,382	$150,735	$314,706,478	$(346,118,985)	$(31,261,769)

See accompanying notes to consolidated financial statements (unaudited).

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

	Nine Months Ended September 30, 2014	2013
Cash flows from operating activities:		
Net loss	$(28,861,683)	$(28,947,577)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	360,702	320,139
Loss on disposal and abandonment of assets	31,794	1,160
Provision for inventory obsolescence	539,027	—
Amortization of debt discount and issuance costs	637,565	501,600
Stock compensation expense	1,032,244	2,193,715
Equity in loss of R-NAV, LLC	262,198	—
Change in fair value of financial instruments	109,499	377,474
Loss on extinguishment of debt	2,610,196	1,372,266
Issued stock to 401(k) plan	100,044	66,777
Changes in operating assets and liabilities:		
Accounts receivable	(314,800)	(49,263)
Inventory	573,191	(1,745,284)
Prepaid expenses and other assets	(109,116)	302,600
Accounts payable	(45,410)	287,312
Accrued and other liabilities	(1,226,288)	862,470
Net cash used in operating activities	(24,300,837)	(24,456,611)
Cash flows from investing activities:		
Purchases of equipment	(1,111,418)	(762,869)
Patent and trademark costs	(51,876)	(28,317)
Investment in R-NAV, LLC	(333,334)	—
Net cash used in investing activities	(1,496,628)	(791,186)
Cash flows from financing activities:		
Proceeds from issuance of common stock and short swing profits	87,982	41,303,738
Payment of common stock issuance costs	—	(1,717,064)
Payment of tax withholdings related to stock-based compensation	(75,759)	(659,018)
Proceeds from notes payable	30,000,000	29,000,000
Payment of debt-related costs	(1,763,526)	(1,177,293)
Principal payments on notes payable	(25,000,000)	(5,982,156)
Payments under capital leases	(1,640)	(6,370)
Net cash provided by financing activities	3,247,057	60,761,837
Net (decrease) increase in cash	(22,550,408)	35,514,040
Cash, beginning of period	32,939,026	9,118,564
Cash, end of period	$10,388,618	$44,632,604

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, 2014 and for the three-month and nine-month periods ended September 30, 2014 and 2013 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, 2014 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, 2013, 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. All significant inter-company accounts were eliminated in consolidation.

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, 2014 and December 31, 2013 primarily consists of the face amount of the notes less unamortized discounts. See Note 8. At September 30, 2014 and December 31, 2013, certain notes payable were also required to be recorded at fair value. The estimated fair value of our debt was calculated using a discounted cash flow analysis as well as a probability-weighted Monte Carlo simulation. These valuation methods include Level 3 inputs such as the estimated current market interest rate for similar instruments with similar creditworthiness. 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, 2014, the fair value of our notes payable is approximately $36.7 million.

(3) Derivative liabilities: Derivative liabilities are related to certain outstanding warrants which are recorded at fair value. The assumptions used to calculate fair value as of September 30, 2014 include 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 consolidated statements of operations. See Notes 2 and 9.

c. Revenue Recognition: We currently generate revenue primarily from sales of Lymphoseek. Our standard shipping terms are FOB shipping point, and title and risk of loss passes to the customer upon delivery to a carrier for shipment from Cardinal Health's national distribution center to another point of destination. We generally recognize sales revenue related to sales of our products when the products are shipped. Our customers have no right to return products purchased in the ordinary course of business.

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

We also earn revenue related to milestones as defined in our distribution agreements. Such revenue is recognized when the milestones are achieved with no future obligations and payments under the agreements become contractually due.

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.

d. Recent Accounting Pronouncements: In May 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2014-09, Revenue from Contracts with Customers. The core principle of ASU 2014-09 is built on the contract between a vendor and a customer for the provision of goods and services. It attempts to depict the exchange of rights and obligations between the parties in the pattern of revenue recognition based on the consideration to which the vendor is entitled. To accomplish this objective, ASU 2014-09 requires five basic steps: (i) identify the contract with the customer, (ii) identify the performance obligations in the contract, (iii) determine the transaction price, (iv) allocate the transaction price to the performance obligations in the contract, (v) recognize revenue when (or as) the entity satisfies a performance obligation. Entities will generally be required to make more estimates and use more judgment than under current guidance, which will be highlighted for users through increased disclosure requirements. ASU 2014-09 is effective for public entities for annual periods beginning after December 15, 2016, including interim periods therein. Three basic transition methods are available - full retrospective, retrospective with certain practical expedients, and a cumulative effect approach. Early adoption is prohibited. We are currently evaluating the impact of our pending adoption of ASU 2014-09 on our consolidated financial statements and have not yet determined the method by which we will adopt the standard in 2017.

In June 2014, the FASB issued ASU No. 2014-12, Compensation-Stock Compensation. ASU 2014-12 requires that a performance target included in a share-based payment award that affects vesting and that could be achieved after the requisite service period be treated as a performance condition. Therefore, under the existing stock compensation guidance in Topic 718, the performance target should not be reflected in estimating the grant-date fair value of the award. Compensation cost should be recognized in the period in which it becomes probable that the performance target will be achieved and should represent the compensation cost attributable to the period(s) for which the requisite service has already been rendered. If the performance target becomes probable of being achieved before the end of the requisite service period, the remaining unrecognized compensation cost should be recognized prospectively over the remaining requisite service period. The total amount of compensation cost recognized during and after the requisite service period should reflect the number of awards that are expected to vest and should be adjusted to reflect those awards that ultimately vest. The requisite service period ends when the employee can cease rendering service and still be eligible to vest in the award if the performance target is achieved. ASU 2014-12 is effective for annual periods beginning after December 15, 2015, including interim periods therein. Earlier adoption is permitted. Entities may apply the amendments in ASU 2014-12 either (a) prospectively to all awards granted or modified after the effective date or (b) retrospectively to all awards with performance targets that are outstanding as of the beginning of the earliest annual period presented in the financial statements and to all new or modified awards thereafter. If retrospective transition is adopted, the cumulative effect of applying ASU 2014-12 as of the beginning of the earliest annual period presented in the financial statements should be recognized as an adjustment to the opening retained earnings balance at that date. Additionally, if retrospective transition is adopted, an entity may use hindsight in measuring and recognizing the compensation cost. We do not expect the adoption of ASU 2014-12 to have a material effect on our consolidated financial statements.

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

2. Fair Value Hierarchy

Platinum-Montaur Life Sciences, LLC (Platinum) has the right to convert all or any portion of the unpaid principal or unpaid interest accrued on any draws subsequent to the second quarter of 2013 under the Platinum credit facility, under certain circumstances. Platinum’s option to convert such subsequent draws into common stock was determined to meet the definition of a liability and is included as part of the value of the related notes payable on the consolidated balance sheets. The estimated fair value of the Platinum notes payable is $4.4 million at September 30, 2014, and will continue to be measured on a recurring basis. See Note 8.

In September 2013, in connection with a Securities Purchase Agreement with Crede CG III, Ltd. (Crede), we issued warrants containing certain features that, although they do not require the warrants to be settled in cash, do require the warrants to be classified as liabilities under applicable accounting rules. As a result, the Company recorded a derivative liability with an estimated fair value of $7.7 million on the date the warrants were issued. The estimated fair value of the liability remained at $7.7 million as of September 30, 2014, and will continue to be measured on a recurring basis. See Notes 1b(3), 9 and 11.

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, 2014

Description	Quoted Prices in Active Markets for Identical Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Balance as of September 30, 2014
Platinum notes payable	$—	$—	$4,372,518	$4,372,518
Derivative liabilities related to warrants	—	7,697,130	—	7,697,130

Liabilities Measured at Fair Value on a Recurring Basis as of December 31, 2013

Description	Quoted Prices in Active Markets for Identical Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Balance as of December 31, 2013
Platinum notes payable	$—	$—	$4,268,062	$4,268,062
Derivative liabilities related to warrants	—	7,692,087	—	7,692,087

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. Valuations using complex models such as Monte Carlo simulations 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 the liabilities. The significant unobservable inputs used in the fair value measurement of the liabilities include the amount and timing of future draws expected to be taken under the Platinum Loan Agreement based on current internal forecasts, management's estimate of the likelihood of actually making those draws as opposed to obtaining other sources of financing, and management's estimate of the likelihood of those draws ultimately resulting in Platinum exercising their conversion option under the Platinum Loan Agreement. Significant increases (decreases) in any of the significant unobservable inputs would result in a higher (lower) fair value measurement. A change in one of the inputs would not necessarily result in a directionally similar change in the others.

There were no Level 1 liabilities outstanding at any time during the three-month and nine-month periods ended September 30, 2014 and 2013. There were no transfers in or out of our Level 2 liabilities during the three-month and nine-month periods ended September 30, 2014 or 2013.

3. Stock-Based Compensation

At September 30, 2014, we have instruments outstanding under three stock-based compensation plans; the 1996 Stock Incentive Plan (the 1996 Plan), the Fourth Amended and Restated 2002 Stock Incentive Plan (the 2002 Plan), and the 2014 Stock Incentive Plan (the 2014 Plan). Currently, under the 2014 Plan, we may grant incentive stock options, nonqualified stock options, and restricted stock awards to full-time employees and directors, and nonqualified stock options and restricted stock awards may be granted to our consultants and agents. Total shares authorized under each plan are 1.5 million shares, 12 million shares, and 5 million shares, respectively. Although instruments are still outstanding under the 1996 Plan and the 2002 Plan, the plans have expired and no new grants may be made from them. Under all 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 1996 Plan, the 2002 Plan, and the 2014 Plan generally vest on an annual basis over one to four years. 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.

Compensation cost arising from stock-based awards is recognized as 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, 2014 and 2013, our total stock-based compensation (income) expense was approximately $(528,000) and $772,000, respectively. For the nine-month periods ended September 30, 2014 and 2013, our total stock-based compensation expense was approximately $1.0 million and $2.2 million, respectively. We have not recorded any income tax benefit related to stock-based compensation in any of the three-month or nine-month periods ended September 30, 2014 and 2013.

A summary of the status of our stock options as of September 30, 2014, and changes during the nine-month period then ended, is presented below:

	Nine Months Ended September 30,			
	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value
Outstanding at beginning of period	4,866,602	$2.38		
Granted	1,509,605	1.76		
Exercised	(343,000)	0.51		
Canceled and Forfeited	(1,467,443)	2.53		
Expired	(120,000)	0.53		
Outstanding at end of period	4,445,764	$2.31	7.4 years	$491,723
Exercisable at end of period	1,958,554	$2.11	5.9 years	$489,240

A summary of the status of our unvested restricted stock as of September 30, 2014, and changes during the nine-month period then ended, is presented below:

	Nine Months Ended September 30,	
	Number of Shares	Weighted Average Grant-Date Fair Value
Unvested at beginning of period	634,250	$2.73
Granted	378,250	1.48
Vested	(149,000)	3.16
Forfeited	(300,000)	2.26
Unvested at end of period	563,500	$2.03

In February 2014, 49,000 shares of restricted stock held by non-employee directors with an aggregate fair value of $96,000 vested as scheduled according to the terms of the restricted stock agreements. In March 2014, 100,000 shares of restricted stock with an aggregate fair value of $205,000 vested as scheduled according to the terms of a restricted stock agreement. In May 2014, 175,000 shares of restricted stock held by our former CEO with an aggregate fair value of $278,000 were forfeited in connection with his separation from employment. In September 2014, 125,000 shares of restricted stock held by our former CEO with an aggregate fair value of $166,250 were forfeited in connection with termination of his Consulting Agreement.

As of September 30, 2014, there was approximately $1.7 million of total unrecognized compensation expense related to unvested stock-based awards, which we expect to recognize over remaining weighted average vesting terms of 1.9 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 securities, options and warrants.

Earnings (loss) per common share for the three-month and nine-month periods ended September 30, 2014 and 2013 excludes the effects of approximately 17.7 million and 33.5 million common share equivalents, respectively, since such inclusion would be anti-dilutive. The excluded shares consist of common shares issuable upon exercise of outstanding stock options and warrants, and upon the conversion of convertible debt and convertible preferred stock.

The Company's unvested stock awards contain nonforfeitable rights to dividends or dividend equivalents, whether paid or unpaid (referred to as "participating securities"). Therefore, the unvested stock awards are required to be included in the number of shares outstanding for both basic and diluted earnings per share calculations. However, due to our loss from continuing operations, approximately 564,000 and 622,000 shares of unvested restricted stock were excluded in determining basic and diluted loss per share for the three-month and nine-month periods ended September 30, 2014 and 2013, respectively, because such inclusion would be anti-dilutive.

5. Inventory

All components of inventory are valued at the lower of cost (first-in, first-out) or market. We adjust inventory to market value when the net realizable value is lower than the carrying cost of the inventory. Market value is determined based on estimated sales activity and margins.

The components of inventory as of September 30, 2014 and December 31, 2013, net of reserves of $539,000 and $0, respectively, are as follows:

	September 30, 2014 (unaudited)	December 31, 2013
Materials	$467,218	$652,818
Work-in-process	—	1,073,568
Finished goods	653,000	506,050
Total	$1,120,218	$2,232,436

During the three-month and nine-month periods ended September 30, 2013, we capitalized $1.0 million and $2.3 million, respectively, of inventory costs associated with our Lymphoseek® (technetium Tc 99m tilmanocept) injection product. The Company capitalized no such costs during the same period in 2014. During the three-month periods ended September 30, 2014 and 2013, we wrote off $66,000 and $298,000, respectively, of previously capitalized Lymphoseek inventory due to the consumption of the Lymphoseek material for product testing and development purposes. During the nine-month periods ended September 30, 2014 and 2013, we wrote off $121,000 and $298,000, respectively, for the same reason.

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. During the nine-month period ended September 30, 2014, we recorded an obsolescence reserve for $539,000 of Lymphoseek inventory that is nearing its product expiry and therefore is no longer expected to be sold.

6. Reduction in Force

In May 2014, the Company's 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. As a part of the realignment, the Company terminated a total of 11 employees, including the Chief Executive Officer, Dr. Mark J. Pykett.

Effective May 30, 2014, the Company and Dr. Pykett entered into a Separation Agreement and Release. Following the termination date, Dr. Pykett is entitled to receive a $750,000 severance payment, payable in two equal installments on June 9, 2014, and January 2, 2015, respectively; a single payment for accrued vacation and personal days; and reimbursement for certain other expenses and fees. Certain of Dr. Pykett's equity awards terminated upon separation, while others were modified in conjunction with the Separation Agreement and the Consulting Agreement described below.

Effective June 1, 2014, the Company and Dr. Pykett entered into a Consulting Agreement pursuant to which Dr. Pykett was to serve as an independent consultant to the Company until December 31, 2014 with respect to clinical-regulatory activities, commercial activities, program management, and business development, among other services. Dr. Pykett was entitled to a consulting fee of $27,500 per month plus reimbursement of reasonable expenses. The Consulting Agreement also provided for a grant of 40,000 shares of restricted stock which were to vest upon certain service and performance conditions.

Dr. Pykett terminated the Consulting Agreement effective September 8, 2014. Certain of Dr. Pykett's equity awards were forfeited upon termination of the Consulting Agreement, while others will vest on December 1, 2014 due to achievement of certain goals during the period of the Consulting Agreement, in accordance with the terms of the award agreements. The Company recognized expense of $63,000 under the Consulting Agreement during the quarter ended September 30, 2014.

The following table summarizes the remaining accrued separation costs, including estimated employer payroll tax obligations, related to the Company's reduction in force, which are included in accrued liabilities and other on the consolidated balance sheet as of September 30, 2014:

	As of September 30, 2014
Separation	$413,469
Estimated cost of continuing healthcare coverage	60,882
	$474,351

During the nine-month period ended September 30, 2014, the Company recognized approximately $557,000 of net expense as a result of the reduction in force, which includes separation costs, incremental expense related to the modification of certain equity awards, and the reversal of stock compensation expense for certain equity awards for which the requisite service was not rendered.

The Company appointed Michael M. Goldberg, M.D., as interim Chief Executive Officer effective May 30, 2014. Dr. Goldberg currently serves as a member of the Board of Directors of the Company and has not received any salary for his service as interim Chief Executive Officer, although the Company agreed to pay Montaur Capital Partners, LLC (Montaur), where Dr. Goldberg is principal, $15,000 per month to cover additional costs and resources Montaur expected to incur or redirect due to the unavailability of Dr. Goldberg's services resulting from his service as interim Chief Executive Officer of Navidea. Dr. Goldberg's service as interim Chief Executive Officer terminated with the appointment of Ricardo J. Gonzalez as the Company's Chief Executive Officer effective October 13, 2014. See Note 14(a).

7. Investment in R-NAV, LLC

In July 2014, Navidea announced that it formed a joint enterprise with Essex Woodlands-backed Rheumco, LLC, to develop and commercialize radiolabeled diagnostic and therapeutic products for rheumatologic and arthritic diseases. The joint enterprise, called R-NAV, LLC (R-NAV), will combine Navidea's proprietary Manocept CD206 macrophage targeting platform and Rheumco's proprietary Tin-117m radioisotope technology to focus on leveraging the platforms across several indications with high unmet medical need:

R-NAV Subsidiary 1A: Detection of RA initially using Tc-99m tilmanocept, commercially known as Lymphoseek,
R-NAV Subsidiary 1B: Combination of the Manocept platform with Tin-117m for detection and treatment of RA,
R-NAV Subsidiary 2: Detection and treatment of human and veterinary osteoarthritis (OA) using the Tin-117m technology, and
R-NAV Subsidiary 3: Treatment of pediatric hemophilic arthropathy (PHA), a rare rheumatologic condition.

Both Rheumco and Navidea have contributed licenses for intellectual property and technology to R-NAV in exchange for common units in R-NAV. Each of the licenses has grant-back provisions with respect to inventions and other intellectual property developed in these programs outside of the exclusive fields of use specified in the license. The contributions of these licenses were recorded using the carryover basis.

R-NAV was initially capitalized through a $4.0 million investment from Infinity Capital III, of Houston-based McRay Money Management, and other third-party private investors, and the technology contributions from Rheumco and Navidea. Navidea has committed an additional $1.0 million investment to be paid over three years, with $333,334 in cash contributed at inception and a promissory note in the principal amount of $666,666, payable in two equal installments on the first and second anniversaries of the transaction. The note will bear interest at the applicable federal rate, currently 0.31% per annum. See Note 8. In exchange for its capital and in-kind investment, the Company received 1,000,000 Series A preferred units of R-NAV (Series A Units). The Company will recognize an additional 500,000 Series A Units for management and technical services associated with the programs described above to be performed by the Company for R-

NAV pursuant to a services agreement. The Series A Units are convertible into common units at the option of the holder for a conversion price of $1 per unit, subject to broad-based weighted average anti-dilution rights.

Navidea initially owns approximately 34% of the combined entity. Joint oversight of R-NAV is shared between Navidea, Rheumco, Infinity Capital, and the other investors. Navidea has three-year call options to acquire, at its sole discretion, all of the equity of Subsidiary 1A for $10.5 million prior to the launch of a Phase 3 clinical trial for its development program, and all of the equity of Subsidiary 1B at fair value upon completion of radiochemistry and biodistribution studies for its development program.

Navidea's investment in R-NAV is being accounted for using the equity method of accounting for investments. In accordance with current accounting guidance, the Company's contributions of cash and note payable totaling $1.0 million were allocated between the investment in R-NAV and the call option on Subsidiary 1A based on the relative fair values of the assets. As a result, we recorded an initial equity investment in R-NAV of $727,000 and a call option asset of $273,000 as non-current assets at the time of the initial investment. The Company's obligation to provide $500,000 of in-kind services to R-NAV will be recognized as those services are provided. Navidea's equity in the loss of R-NAV was $262,000 for the three-month period ended September 30, 2014.

8. Notes Payable

In March 2014, we executed a Loan and Security Agreement (the Oxford Loan Agreement) with Oxford Finance, LLC (Oxford), providing for a loan to the Company of $30 million. Pursuant to the Oxford Loan Agreement, we issued Oxford: (1) Term Notes in the aggregate principal amount of $30,000,000, bearing interest at 8.5% (the Oxford Notes), and (2) Series KK warrants to purchase an aggregate of 391,032 shares of our common stock at an exercise price of $1.918 per share, expiring in March 2021 (the Series KK warrants). We will make monthly payments of interest only commencing on April 1, 2014, and continuing through April 1, 2015 (the Amortization Date, which may be extended to April 1, 2016, and again to April 1, 2017, if the Company achieves certain milestones associated with the Company’s Lymphoseek product). Commencing on the Amortization Date, the Company will make consecutive equal monthly payments of principal and interest, in arrears, to the lenders then party to the Oxford Loan Agreement based on a repayment schedule of 48 months if the Amortization Date is April 1, 2015, 36 months if the Amortization Date is April 1, 2016, and 24 months if the Amortization Date is April 1, 2017. All unpaid principal, and accrued and unpaid interest, with respect to the Oxford Notes is due and payable in full on March 1, 2019. We will also make a final payment to the lenders in an aggregate amount equal to the original principal amount of the loan multiplied by 7.95% if the Amortization Date is April 1, 2015; 8.95% if the Amortization Date is extended to April 1, 2016; or 9.95% if the Amortization Date is extended to April 1, 2017. The Oxford Notes are collateralized by a security interest in substantially all of the Company’s assets except for intellectual property, as to which the security interest is in rights to income or proceeds from the sale or licensing thereof. The Oxford Loan Agreement requires that the Company adhere to certain affirmative and negative covenants, including, without limitation, financial reporting requirements and a prohibition against the incurrence of indebtedness, or creation of additional liens, other than as specifically permitted by the terms of the Oxford Loan Agreement. As of September 30, 2014, the outstanding principal balance of the Oxford Loan Agreement was $30 million, and we were in compliance with all covenants of the Oxford Loan Agreement.

The Company recorded a debt discount related to the issuance of the Series KK Warrants and other fees to the lenders totaling $3.0 million. Debt issuance costs directly attributable to the Oxford Loan Agreement, totaling $120,000, were recorded as a non-current asset on the consolidated balance sheet on the closing date. The debt discount and debt offering costs are being amortized as non-cash interest expense using the effective interest method over the term of the Oxford Loan Agreement. As of September 30, 2014, the balance of the debt discount was $2.6 million, and the balance of the debt issuance costs was $99,000.

Also in March 2014, in connection with the consummation of the Oxford Loan Agreement, we repaid all amounts outstanding under the General Electric Capital Corporation (GECC) and MidCap Financial SBIC, LP (MidCap) Loan and Security Agreement for a payoff amount of $26.7 million, which included payments of $500,000 as a pre-payment fee and $1,000,000 as an end-of-term final payment fee.

In March 2014, in connection with entering into the Oxford Loan Agreement, we entered into a second amendment to the Platinum Loan Agreement (the Second Platinum Amendment). Concurrent with the execution of the Second Platinum Amendment, the Company delivered an Amended and Restated Promissory Note (the Second Amended Platinum Note) to Platinum, which amended and restated the First Amended Platinum Note. The Second Amended Platinum Note adjusted the interest rate to the greater of (i) the United States prime rate as reported in The Wall Street Journal plus 6.75%, (ii) 10.0%, and (iii) the highest rate of interest then payable by the Company pursuant to the Oxford Loan Agreement plus

0.125% (the effective interest rate at September 30, 2014 was 10.0%). Navidea, Platinum, and Oxford also entered into a Subordination Agreement, providing for subordination of the Company's indebtedness under the Platinum Loan Agreement to the Company's indebtedness under the Oxford Loan Agreement, among other customary terms and conditions. As such, no payments may be made under the Platinum loan until the Oxford Notes have been paid in full and therefore, the current balance outstanding under the Platinum loan has been classified as long-term notes payable to coincide with the maturity of the Oxford Notes. The fair value of the Second Amended Platinum Note includes the estimated fair value of an embedded conversion option. The net increase in the estimated fair value of the Second Amended Platinum Note of $104,000 was recorded as a non-cash change in fair value of financial instruments during the nine-month period ended September 30, 2014. The estimated fair value of the Second Amended Platinum Note was $4.4 million as of September 30, 2014. As of September 30, 2014, the remaining outstanding principal balance of the Second Amended Platinum Note was approximately $3.2 million, with $31.8 million still available under the credit facility.

In July 2014, in connection with entering into the R-NAV joint enterprise, Navidea executed a promissory note in the principal amount of $666,666, payable in two equal installments on July 15, 2015 and July 15, 2016, the first and second anniversaries of the R-NAV transaction. The note will bear interest at the applicable federal rate, currently 0.31% per annum, compounded annually. Also in connection with entering into the R-NAV joint enterprise, we executed an amendment to the Oxford Loan Agreement that amended certain covenants to permit our investment in R-NAV, and R-NAV entered into a Subordination Agreement with Oxford to subordinate our indebtedness to R-NAV to our obligations under the Oxford Loan Agreement. See Note 7.

During the three-month periods ended September 30, 2014 and 2013, we recorded interest expense of $921,000 and $976,000, respectively, related to our notes payable. Of these amounts, $201,000 and $258,000, respectively, related to amortization of the debt discounts and deferred financing costs related to our notes payable. During the nine-month periods ended September 30, 2014 and 2013, we recorded interest expense of $2.8 million and $1.8 million, respectively, related to our notes payable. Of these amounts, $638,000 and $502,000, respectively, related to amortization of the debt discounts and deferred financing costs related to our notes payable.

9. Derivative Instruments

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

At September 30, 2014, derivative liabilities consist of the Series JJ warrants issued to Crede in September 2013. The net effect of marking the Company's derivative liabilities to market during the three-month and nine-month periods ended September 30, 2014 resulted in net increases in the estimated fair values of the derivative liabilities of approximately $8,000 and $5,000, respectively, which were recorded as non-cash changes in the fair value of financial instruments. The total estimated fair value of our derivative liabilities was $7.7 million as of September 30, 2014. See Notes 1b(3) and 2.

10. Equity

During the nine-month period ended September 30, 2014, Platinum converted 4,422 shares of their Series B Preferred Stock into 14,459,940 shares of our common stock under the terms of the Series B Preferred Stock. As of September 30, 2014, there are 3,143 shares of Series B Preferred Stock outstanding which are convertible into 10,277,610 shares of our common stock.

11. Stock Warrants

In March 2014, in connection with the Oxford Loan Agreement, the Company issued 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.

At September 30, 2014, there are 4.9 million warrants outstanding to purchase our common stock. The warrants are exercisable at prices ranging from $1.918 to $3.83 per share with a weighted average exercise price of $3.27 per share. See Note 2.

12. Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases, and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. Due to the uncertainty surrounding the realization of the deferred tax assets in future tax returns, all of the deferred tax assets have been fully offset by a valuation allowance at September 30, 2014 and December 31, 2013.

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, 2014 or December 31, 2013 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, 2014, tax years 2010-2013 remained subject to examination by federal and state tax authorities.

13. Supplemental Disclosure for Statements of Cash Flows

During the nine-month periods ended September 30, 2014 and 2013, we paid interest aggregating $2.1 million and $1.2 million, respectively. During the nine-month periods ended September 30, 2014 and 2013, we issued 36,455 and 22,126 shares of our common stock, respectively, as matching contributions to our 401(k) plan.

In connection with entering into the Oxford Loan Agreement, we issued warrants with an estimated relative fair value of $465,000. In conjunction with the GECC Loan Agreement, we issued warrants with a fair value of $631,000. In connection with entering into the Crede Securities Purchase Agreement, we issued warrants with an estimated fair value of $7.7 million.

In connection with entering into the R-NAV joint enterprise, Navidea executed a promissory note in the principal amount of $666,666, payable in two equal installments on July 15, 2015 and July 15, 2016, the first and second anniversaries of the R-NAV transaction. See Notes 7 and 8.

14. Subsequent Events

a. Appointment of Chief Executive Officer: In October 2014, Ricardo J. Gonzalez was appointed Chief Executive Officer of Navidea. In connection with the Board of Directors' appointment of Mr. Gonzalez as Chief Executive Officer, the Company and Mr. Gonzalez have entered into a three-year employment agreement (the Employment Agreement). The Employment Agreement provides for an initial annual base salary of $375,000 and a potential performance bonus of up to 50% of the base salary as well as severance and other standard employment benefits. As an inducement for Mr. Gonzalez to join the Company and as additional compensation, the Board of Directors awarded him options to purchase 1,000,000 shares of the Company's common stock at an exercise price of $1.26 per share (the Option Agreement). These options vest over a three-year period, subject to certain service and market conditions as defined in the Option Agreement.

b. Notice of Refund of FDA Filing Fee: During the third quarter of 2014, the FDA granted Orphan Drug Designation for use of Lymphoseek 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 Prescription Drug User Fee Act (PDUFA) filing fees. In October 2014, Navidea was notified that the FDA will refund the previously paid PDUFA filing fees of approximately $1.1 million during the fourth quarter of 2014.

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. (Navidea, the Company, or we), a Delaware corporation, is a biopharmaceutical company focused on the development and commercialization of precision diagnostics. We have five pharmaceutical platforms in various stages of development:

- Lymphoseek® (technetium Tc 99m tilmanocept) injection is a novel, receptor-targeted, small-molecule radiopharmaceutical used in lymphatic mapping procedures that are performed to help evaluate patients with breast cancer or melanoma. Lymphoseek is designed to identify the lymph nodes that drain from a primary tumor, which have the highest probability of harboring cancer. It was approved by the U.S. Food and Drug Administration (FDA) in March 2013, and launched commercially in the United States in May 2013.
- Navidea’s Manocept™ platform is predicated on the ability of the backbone of tilmanocept to specifically target the CD206 mannose receptor expressed on macrophages. Building on the success of Lymphoseek, this flexible and versatile 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.
- 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).
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- 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.
- NAV1800 (formerly RIGScan™) is currently undergoing a transformation in its development. Previously, NAV1800 was being developed using a monoclonal antibody as a diagnostic aid for imaging and use during surgery to help surgeons locate occult or metastatic cancer, with a primary focus on colorectal cancer. We now believe that tilmanocept's ability to target tumor associated macrophages may be a more appropriate targeting agent and are modifying development activities to support that initiative.

The last four of these drug product platforms are in development and must be cleared for marketing by the appropriate regulatory authorities before they can be sold in any markets.

Product Line Overview

Our primary development efforts over the last few years have been focused on the development of our now-approved Lymphoseek product, as well as more recently on our other pipeline programs, including NAV4694, NAV5001, NAV1800, 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 primarily involves reducing our near-term support for our two neurological product candidates, NAV4694 and NAV5001, as we seek to secure a development partner or partners for these programs. The Company is also working to establish new sources of non-dilutive funding, including collaborations 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 recently announced R-NAV venture, which we believe may further expand the Company's pipeline but which require less near-term funding from Navidea than the two ongoing Phase 3 neurological development programs.

Navidea remains committed to expanding the Lymphoseek label and realizing the full potential of the product. We intend to work closely with our partners to continue the strong growth of this important product. The Company believes that the resources being devoted to drive Lymphoseek sales will lead to cash flows that can ultimately fund developmental stage programs from cash flow from operations. The Company is focused on expanding the market for Lymphoseek in all relevant markets.

We expect our overall research and development expenditures to be lower during the remainder of 2014 as compared to 2013 due to the refocusing efforts outlined above, as we reduce the near-term scope of development of NAV4694, NAV5001, and NAV1800, and allocate our resources to personnel, contractors and consultants supporting the global registration and commercialization of Lymphoseek, and development of our Manocept platform.

Lymphoseek

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 December 2013, the FDA granted Fast Track designation to Lymphoseek for sentinel lymph node detection in patients with head and neck cancer and we submitted a supplemental New Drug Application (sNDA) with the FDA seeking approval for the marketing and sale of Lymphoseek for the same indication. In assessing the data-rich submission, the FDA chose to separate the filing into two applications based on the proposed labeling extensions requested and the scope of information provided. The first sNDA, aimed at Lymphoseek’s use as a sentinel lymph node detection agent in patients with head and neck cancer, was accepted for review by the FDA in February 2014, and was granted Priority Review. Under the Prescription Drug User Fee Act (PDUFA), the FDA set a target review date for the first sNDA of June 16, 2014. On June 13, 2014, the FDA approved the first 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, making Lymphoseek the first and only FDA-approved radiopharmaceutical application for sentinel lymph node detection. 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. Navidea expects to receive a refund of the previously paid filing fees of $1.1 million in the fourth quarter of 2014.

In March 2014, the FDA accepted for review the second sNDA to support broader and more flexible use of Lymphoseek in imaging and lymphatic mapping procedures, including lymphoscintigraphy and other product capabilities. Under PDUFA, the FDA set a target review date for the second sNDA of October 16, 2014. On October 15, 2014, the FDA approved the second sNDA for lymphatic mapping in solid tumors and adding sentinel lymph node detection for breast cancer and melanoma to the approved indications. The FDA also allowed expanded utilization of Lymphoseek with or without scintigraphic imaging, known as lymphoscintigraphy, to enable pre-operative imaging and mapping of lymph nodes to facilitate node localization during surgical procedures. Lymphoseek is now the first and only FDA-approved radiopharmaceutical agent for sentinel lymph node detection and is the only FDA-approved agent for lymphatic mapping of solid tumors. Additional trials, including an ongoing trial in colorectal cancer, and others in various stages of execution, planning or consideration, are anticipated to provide additional data to potentially support expansion of the Lymphoseek opportunity.

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In March 2014, we announced results of a three-year, voluntary follow-up study of Lymphoseek conducted in patients who participated in a Phase 3 clinical trial (NEO3-05) of the product. The primary objective of the follow-up study was to determine the regional recurrence-free rate (RRFR) after sentinel lymph node biopsy with Lymphoseek. Results of the follow-up study indicated that in patients who were confirmed to be node-negative after sentinel lymph node biopsy (n=88; 49 breast cancer, 39 melanoma) the RRFR was 98.8% (100% in breast cancer; 97.4% in melanoma) and the disease-specific survival rate was 98.6% (97.8% in breast cancer; 100% in melanoma) at three years.

In June 2014, the Company announced results from combined analyses of Phase 3 clinical trials that evaluated Lymphoseek efficacy in lymphatic mapping for identifying pathology-positive lymph nodes across multiple solid tumor types: melanoma, breast cancer and head and neck squamous cell carcinoma. The results indicated that Lymphoseek sensitivity for sentinel lymph node mapping was consistent across the tumor type studies, regardless of whether surgery was conducted on the same day as, or on the day after, injection of Lymphoseek. Additionally, for patients with head and neck cancer, Lymphoseek demonstrated a low false negative rate (FNR) of 2.6% (4.6% for same day injection before surgery and 0.0% FNR in patients injected the day prior to surgery). Results from the study comprise part of an sNDA filing for Lymphoseek which is under review by the FDA.

Also in June 2014, we announced results from a post-hoc analysis of patient data from the Company’s Phase 3 clinical trial (NEO3-06) of Lymphoseek in head and neck cancer. In the NEO3-06 Phase 3 study, Lymphoseek localization to lymph nodes showed a strong correlation with a full regional lymph node dissection and pathology analysis with a low false negative rate, a priority in identifying sentinel nodes. Lymphoseek was also observed to home preferentially to pathology-positive nodes at a higher rate than pathology-negative nodes. These results suggest that Lymphoseek not only effectively targets sentinel lymph nodes, but further that its ability to highlight tumor-positive lymph nodes may be augmented mechanistically by the recruitment of macrophages to cancer-harboring lymph nodes.

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

In September 2014, Navidea received a notice of award for a Fast Track Small Business Innovation Research (SBIR) grant providing for up to $1.67 million from the National Cancer Institute National Institutes of Health (NIH), to fund evaluation of Lymphoseek in women with cervical cancer. The multicenter clinical study in patients with early cervical cancer will seek to assess and provide data in support of the use of Lymphoseek in sentinel lymph node biopsy procedures which identify and evaluate the lymph nodes most likely to harbor additional cancer. The SBIR grant is awarded in two parts with the potential for total grant money up to $1.67 million over two and a half years. The first six-month funding segment of $165,917, which has already been awarded, is expected to enable Navidea to identify and qualify trial sites and secure necessary contracts 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 sentinel lymph node procedures and pathology evaluations, and perform data analyses to confirm the safety and effectiveness of Lymphoseek.

In July 2014, we amended our license agreement with UCSD for the exclusive world-wide rights to Lymphoseek. The amended license agreement is effective until the third anniversary of the expiration date of the longest-lived underlying patent. Under the terms of the license agreement, UCSD has granted us the exclusive rights to make, use, sell, offer for sale and import licensed products as defined in the agreement and to practice the defined licensed methods during the term of the agreement. We may also sublicense the patent rights, subject to certain sublicense terms as defined in the agreement. In consideration for the license rights, we agreed to make payments to UCSD upon successfully reaching certain clinical, regulatory and cumulative sales milestones, and a royalty on net sales of licensed products subject to a $25,000 minimum annual royalty. We also agreed to reimburse UCSD for all patent-related costs and to meet certain diligence targets.

We are currently pursuing registration of Lymphoseek in the European Union (EU). We submitted our Marketing Authorization Application (MAA) for Lymphoseek to the European Medicines Agency (EMA) in December 2012. In December 2013, the EMA provided updated feedback on the MAA as it continued its review. The updated feedback was limited to supplemental product specification data and the NEO3-06 Phase 3 study in head and neck cancer. In March 2014, we held an update meeting with the EMA where we presented oral explanations to the Committee for Medicinal Products for Human Use (CHMP) relating to open questions on the Lymphoseek MAA. At the conclusion of the meeting, the CHMP informed Navidea that the Committee would continue with its review of the MAA and provided the Company with additional questions, which we addressed. In April 2014, the Company announced its expectation that the CHMP would convene a meeting of the Scientific

Advisory Group on Oncology (SAG-O) to discuss additional elements of the Lymphoseek clinical study in patients with head and neck cancer to provide an opportunity for Navidea and independent experts in head and neck cancer surgery to review clinical data in the MAA filing and discuss broad aspects of care for patients with head and neck cancer in Europe. In September 2014, the CHMP adopted a positive opinion recommending marketing authorization for Lymphoseek for use in imaging and intraoperative detection of sentinel lymph nodes draining a primary tumor in adult patients with breast cancer, melanoma, or head and neck oral cavity squamous cell carcinoma in the EU. The CHMP's positive opinion will be 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. Navidea expects the EC to issue its final decision on the marketing authorization for Lymphoseek during the fourth quarter of 2014.

In August 2014, Navidea entered into an exclusive agreement with a wholly-owned subsidiary of Hainan Sinotau Pharmaceutical Co., Ltd. (Sinotau), a pharmaceutical organization with a broad China focus in oncology and other therapeutic areas, who will develop and commercialize Lymphoseek in China. In exchange, Navidea will earn revenue based on unit sales to Sinotau, a royalty based on Sinotau’s sales of Lymphoseek and up to $2.5 million in milestone payments from Sinotau, including a $300,000 non-refundable upfront payment. As part of the agreement, Sinotau is responsible for costs and conduct of clinical studies and regulatory applications to obtain Lymphoseek approval by the China Food and Drug Administration (CFDA). Upon approval, Sinotau will be responsible for all Lymphoseek sales, marketing, market access and medical affairs activities in China and excluding Hong Kong, Macau and Taiwan. Navidea and Sinotau will jointly support certain pre-market planning activities with a joint commitment on clinical and market development programs pending CFDA approval. In addition to the $300,000 upfront payment, Navidea is eligible for $700,000 in milestone payments up to and through product approval, and an additional $1.5 million in sales milestones. We cannot assure you that Lymphoseek will achieve regulatory approval in the EU, China, or any other market outside the U.S., or if approved, that it will achieve market acceptance in any market.

Manocept Platform

Navidea’s Manocept platform is predicated on the ability to specifically target the CD206 mannose receptor expressed on macrophages. Macrophages play important roles in many disease states and are an emerging target in many diseases where diagnostic uncertainty exists. This flexible and versatile platform serves as an engine for purpose-built molecules that may enhance diagnostic accuracy, clinical decision-making and ultimately patient care, while offering the potential to utilize a breadth of diagnostic modalities, including SPECT, PET, intra-operative and/or optical-fluorescence detection, as well as potentially in the delivery of therapeutic compounds targeting macrophages and their role in a variety of immune- and inflammation-based disorders. The Company’s FDA-approved precision diagnostic lymphatic mapping agent, Lymphoseek, is representative of the ability to successfully exploit this mechanism to develop powerful new products.

In February 2014, data utilizing compounds from our Manocept platform in models of rheumatoid arthritis (RA) were presented by representatives from The Ohio State University at a Keystone Symposia on Molecular Cell Biology of Macrophages in Human Disease. The studies demonstrate the ability of fluorescent Cy3-tilmanocept to identify and localize to disease-state macrophages when administered intravenously, enabling detection of immune-mediated arthritis in affected joints in vivo in mice. Results were confirmed using histopathology. The data highlighted the identification of immune-mediated inflammation seen in arthritic joints of arthritis-affected mice but not in control mice or un-affected joints within arthritis-affected mice. The imaging results in this study showed preferential localization of macrophages by Cy3-tilmanocept in affected joints with little to no localization in unaffected joints.

In April 2014, collaborators from the University of California, San Francisco presented results at the 2014 American Association for Cancer Research conference, highlighting the potential utility of imaging agents derived from the Manocept platform in identifying affected tissues and lymph nodes in patients with Kaposi's Sarcoma (KS). The investigators concluded that, based on the results obtained, labeled imaging agents from the CD206-targeting Manocept platform provide potential avenues to enhance diagnosis and staging in this disorder.

In July 2014, Navidea announced that it formed a joint enterprise with Essex Woodlands-backed Rheumco, LLC, to develop and commercialize radiolabeled diagnostic and therapeutic products for rheumatologic and arthritic diseases. The joint enterprise, called R-NAV, LLC (R-NAV), will combine Navidea's proprietary Manocept CD206 macrophage targeting platform and Rheumco's proprietary Tin-117m radioisotope technology to focus on leveraging the platforms across several indications with high unmet medical need. See Liquidity and Capital Resources - Investment in R-NAV, LLC.

Also in July 2014, the Company completed a license agreement with UCSD for the exclusive world-wide rights in all diagnostic and therapeutic uses of tilmanocept. The license agreement is effective until the third anniversary of the expiration date of the longest-lived underlying patent. Under the terms of the license agreement, UCSD has granted us the exclusive rights to make, use, sell, offer for sale and import licensed products as defined in the agreement and to practice the defined licensed methods during the term of the agreement. We may also sublicense the patent rights, subject to certain sublicense terms as defined in the agreement. In consideration for the license rights, we agreed to pay UCSD a license issue fee of $25,000 and license maintenance fees of $25,000 per year. We also agreed to make payments to UCSD upon successfully reaching certain clinical, regulatory and cumulative sales milestones, and a royalty on net sales of licensed products subject to a $25,000 minimum annual royalty. We also agreed to reimburse UCSD for all patent-related costs and to meet certain diligence targets.

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 (Fujiwara, et al., “Macrophages in inflammation," Curr Drug Targets Inflamm Allergy 2005 June;4(3):281-6).

Impairment of the macrophage-driven disease mechanism 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 RA, atherosclerosis/vulnerable plaque, Crohn’s disease, tuberculosis (TB), systemic lupus erythematosis, KS, and others that span clinical areas in oncology, autoimmunity, infectious diseases, cardiology, and inflammation. Data from studies using agents from the Manocept platform in RA, KS and TB were published in a special supplement, Nature Outlook: Medical Imaging, in Nature’s October 31, 2013 issue. The supplement included a White Paper by Navidea entitled "Innovations in receptor-targeted precision imaging at Navidea: Diagnosis up close and personal," focused on the Manocept platform.

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

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.

Based on the data accumulated to date, NAV4694 appears to have better sensitivity and specificity in detecting beta-amyloid than other agents in its category. Due to its high affinity for amyloid, improved contrast, and enhanced uptake in the amyloid-target regions of interest in the brain compared with low uptake in white matter background, better signal-to-noise ratios have been observed. Greater contrast may enable the ability to detect smaller amounts of amyloid and earlier identification of disease, as well as the opportunity to detect smaller changes in amyloid levels and monitor disease progression over time.

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.

During 2013, we initiated a Phase 2b trial in subjects with MCI and a Phase 3 autopsy-based trial to support registration in the U.S. and the EU. During the first quarter of 2014, we reported data from a blinded read of over 160 cases in which NAV4694 showed sensitivity and specificity both in excess of 95%. Positive results were also reported from our Phase 2b trial in subjects with MCI, showing the agent’s ability to identify beta-amyloid with a high confidence of diagnosis in these are early-stage patients for whom diagnostic uncertainty is often significant. These data build on prior work showing that NAV4694 can separate MCI patients with high beta amyloid who are likely to progress to AD from those who do not. To date, the product candidate appears to be safe and well-tolerated. We cannot assure you, however, that further clinical trials for this product will be successful, that the product will achieve regulatory approval, or if approved, that it will achieve market acceptance.

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 involves reducing our near-term support for our neurological product candidates, including NAV4694, as we seek to secure a development partner or partners for these programs.

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.

Results from clinical trials to date have demonstrated that NAV5001 has high affinity for DAT and rapid kinetics which enable the generation of clean images quickly, beginning within about 20 minutes after injection, while other agents have waiting periods from 4 to 24 hours before imaging can occur. 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 December 2013, we announced the initiation of our pivotal Phase 3 registration program to assess the safety and efficacy of NAV5001 as an aid in the differential diagnosis of Parkinsonian Syndromes from non-Parkinsonian tremor. This clinical study is focused on subjects with emerging symptoms in whom diagnostic uncertainty and unmet need are highest. Results from earlier trials using NAV5001 suggest that it is an effective, well-tolerated imaging agent. The agent's high affinity for DAT and resulting clear images can assist physicians in reaching an accurate diagnosis sooner, and the rapid kinetics with minimal time between injection and scanning and time in the SPECT scanner not only decrease patient exposure and but also facilitate increased efficiency with potential cost savings for the nuclear medicine facility. Reducing diagnostic uncertainty and error rates for patients with movement disorders who often exhibit similar clinical symptoms has the potential to afford great value, especially early in the initial clinical presentation, and may lead to improved clinical decision-making and patient management. We cannot assure you, however, that further clinical trials for this product will be successful, that the product will achieve regulatory approval, or if approved, that it will achieve market acceptance.

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 involves reducing our near-term support for our neurological product candidates, including NAV5001, as we seek to secure a development partner for these programs.

NAV1800

Over the course of the last few years, management has provided periodic updates regarding the status of the NAV1800 development program we formerly referred to as the RIGS program, or radio-immuno-guided surgery. NAV1800 was intended to aid in identifying a primary tumor, ascertaining tumor margins, or determining the extent and location of occult and metastatic tumor in patients with solid tumor cancers, such as colorectal cancer, ovarian cancer, prostate cancer, lung cancer and other cancers of epithelial origin. The detection of clinically occult tumor is intended to provide the surgeon with a more accurate assessment of the extent and location of disease, and therefore may impact the surgical and therapeutic management of the patient.

Our most recent comments regarding NAV1800 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. Part of our ongoing consideration of the RIGS program has involved an evaluation of the manufacturability of the monoclonal antibody known as CC49 and its humanized derivative, and ultimately their clinical and commercial viability. In recent years, these evaluations have caused us to question the viability of the monoclonal antibody initiative as it was originally envisioned. During the same time period, we’ve learned more about tilmanocept, the underlying Manocept backbone, and the potential utility of tilmanocept in identifying tumor-associated macrophages (TAMs), and their consequent potential utility in identifying tumor itself. To that end, we petitioned the NIH to repurpose the grant we were previously awarded towards the study of TAMs in colorectal cancer. We recently received confirmation of the acceptance of this repurposing. We expect this repurposed grant will now support the collaboration we entered into in November 2013 with investigators at the University of Alabama at Birmingham (UAB) to assess diagnostic approaches in colorectal cancer patients. We recognize this repurposing represents a major refocusing of the original RIGS initiative, but we are confident that this change represents the best course of action at this time towards benefiting patients afflicted with colorectal cancer and is one which is consistent with the excitement we’re seeing on many fronts related to our work on the Manocept platform. However, we cannot assure you that if further clinical trials for this product proceed, that they will be successful, that the product will achieve regulatory approval, or if approved, that it will achieve market acceptance.

Outlook

Following the U.S. approval of Lymphoseek in March 2013, the Company undertook the initial stages of product launch in the U.S. with our commercialization partner, Cardinal Health, in May 2013. We began reporting revenue from Lymphoseek beginning in the second quarter of 2013, though revenue for that quarter consisted primarily of inventory stocking of Cardinal Health's nuclear pharmacies. As insight into the sales process with Lymphoseek has grown over the periods following launch, we initially announced our expectation for revenue to Navidea from Lymphoseek to be between $5 million and $6 million for 2014. Based on Lymphoseek revenue year-to-date and anticipated fourth quarter 2014 product sales, Navidea has reduced its Lymphoseek revenue guidance for the full year 2014 to approximately $4 million.

Our operating expenses in recent years have been focused primarily on support of Lymphoseek, our Manocept platform, NAV4694 and NAV5001 product development, and to a lesser extent, on efforts related to NAV1800. We incurred approximately $14.5 million and $14.3 million in total on research and development activities during the nine-month periods ended September 30, 2014 and 2013, respectively. Of the total amounts we have 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	2014	2013
Lymphoseek	$1,669,421	$1,941,110
Manocept Platform	453,311	320,774
NAV4694	5,414,838	5,325,207
NAV5001	1,198,313	739,677
NAV1800	34,393	66,031

Due to the advancement of our efforts with Lymphoseek and our Manocept platform, offset by reductions in development of NAV4694, NAV5001, and NAV1800, we expect our total research and development expenses for 2014 to be in the range of approximately $18 million to $20 million. The levels of program expenditures will depend in part on efforts associated with advancing Lymphoseek and deccelerating enrollment and other activities related to our NAV4694 program. In general, development expenses for Lymphoseek in 2014 are expected to decrease as compared to 2013. We also expect expenses for NAV4694, NAV5001 and NAV1800 to be reduced overall during the remainder of 2014 and into 2015, commensurate with management of our available resources.

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. Although our marketing partner will bear much of the direct marketing, sales and distribution costs related to the sale of Lymphoseek, we expect to incur ongoing costs to support product launch, general marketing efforts, and targeted high-volume account sales activities, 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 potential label expansion for the use of Lymphoseek in additional cancer types. We cannot assure you that Lymphoseek will achieve regulatory approval in the EU or any other market outside the U.S., or if approved in those markets, that it will achieve market acceptance in the U.S. 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.

As discussed above, we expect to reduce our expenses for NAV4694 and NAV5001 during the remainder of 2014 following the May 2014 Board decision to refocus the Company's efforts on Lymphoseek and Manocept platform development. During 2013, we were awarded two SBIR grants from the NIH in connection with our clinical programs for NAV4694, the first to support our Phase 3 trial of NAV4694 as an aid in the differential diagnosis of AD, and the second to support our Phase 2b trial of NAV4694 as a diagnostic imaging agent that may aid physicians in identifying individuals with MCI who are at greatest risk of progressing to AD. These SBIR grants have the potential to provide up to $1.8 million and $2.3 million in support, respectively, if fully funded, through the conclusion of the clinical studies. Currently, neither NAV4694 nor NAV5001 is expected to contribute revenue to the Company until 2017, at the earliest. We cannot assure you that further clinical trials for these products will be successful, that the agents will ultimately achieve regulatory approval, or if approved, the extent to which they will achieve market acceptance.

As discussed previously, we have recently changed our focus on the NAV1800 program from one focused on development of a monoclonal antibody to an approach focused on expanding the use of our Manocept platform in the identification of TAMs as they relate to potential metastatic disease spread from colorectal and other cancers. In the near-term, our development efforts related to NAV1800 will likely continue to be limited to those which we are able to fund through external sources such as the SBIR grant from the NIH we were awarded in 2012. We cannot assure you that we will be able to complete satisfactory development arrangements or obtain incremental financing to fund the NAV1800 program and cannot guarantee that such arrangements could be obtained on a timely basis on terms acceptable to us, or at all. We also cannot assure you that further clinical development will be successful, that the agent will ultimately achieve regulatory approval, or if approved, that it will achieve market acceptance.

Finally, if we are successful in identifying and securing additional product candidates to augment our product development pipeline, we will likely incur significant additional expenses related to furthering the development of such products.

Results of Operations

Three Months Ended September 30, 2014 and 2013

Lymphoseek Sales and Margins. Net sales of Lymphoseek realized by Navidea were $1.1 million during the third quarter of 2014, as compared to $144,000 during the third quarter of 2013. The increase was primarily due to sales starting in late April of 2013, coupled with an increase in the initial transfer price to Cardinal beginning in the second quarter of 2014. Gross margins on net sales were 27% and 48% for the third quarters of 2014 and 2013, respectively. 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 is nearing its product expiry and therefore is no longer expected to be sold. Excluding the one-time inventory obsolescence charge, gross margin for the third quarter of 2014 would have been 76%. 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 Milestone Revenue. During the third quarter of 2014, we recognized $300,000 of Lymphoseek milestone revenue from a non-refundable upfront milestone payment received by the Company related to the recent Lymphoseek distribution agreement for China for which the Company has no future obligations. No Lymphoseek milestone revenue was recognized during the third quarter of 2013.

Grant and Other Revenue. During the third quarter of 2014, we recognized $849,000 of grant and other revenue as compared to $257,000 in the third quarter of 2013, primarily related to SBIR grants from the NIH supporting NAV4694 and NAV1800 development. The net increase was primarily due to higher NAV4694 grants offset by lower NAV1800 and Lymphoseek grants. Grant and other revenue for the third quarter of 2014 also included revenue related to services provided to R-NAV for Manocept development.

Research and Development Expenses. Research and development expenses decreased $2.1 million, or 34%, to $4.2 million during the third quarter of 2014 from $6.3 million during the same period in 2013. The decrease was primarily due to net decreases in drug project expenses related to (i) decreased NAV4694 development costs of $1.1 million including decreased manufacturing-related activities coupled with decreased clinical trial and regulatory costs, (ii) decreased Manocept platform development costs of $213,000, and (iii) decreased Lymphoseek development costs of $159,000. The net decrease in research and development expenses also included decreased compensation including incentive-based awards and other expenses related to net decreased headcount related to the second quarter 2014 reduction in force.

Selling, General and Administrative Expenses. Selling, general and administrative expenses decreased $1.3 million, or 33%, to $2.6 million during the third quarter of 2014 from $4.0 million during the same period in 2013. The net decrease was primarily due to decreased compensation including incentive-based awards and other expenses related to net decreased headcount related to the second quarter 2014 reduction in force.

Other Income (Expense). Other expense, net, was $1.5 million during the third quarter of 2014 as compared to $1.4 million during the same period in 2013. Interest expense decreased $55,000 to $921,000 during the third quarter of 2014 from $976,000 for the same period in 2013, primarily due to lower interest related to the Oxford Note in 2014, offset by higher interest GECC/MidCap Notes in 2013. Of this interest expense, $201,000 and $258,000 in the third quarter of 2014 and 2013, respectively, was non-cash in nature related to the amortization of debt issuance costs and non-cash debt discounts related to the Oxford and GECC/MidCap Notes. For the third quarter of 2014, we recorded non-cash expense of $410,000 related to changes in the estimated fair value of financial instruments as compared to $377,000 during the same period in 2013. During the third quarter of 2014, we recorded non-cash expense from our equity in the loss of R-NAV of $262,000.

Nine Months Ended September 30, 2014 and 2013

Lymphoseek Sales and Margins. Net sales of Lymphoseek realized by Navidea were $2.8 million during the first nine months of 2014, as compared to $272,000 during the first nine months of 2013. The increase was primarily due to sales starting in late April of 2013, coupled with an increase in the initial transfer price to Cardinal beginning in the second quarter of 2014. Gross margins on net sales were 54% and 33% for the first nine months of 2014 and 2013, respectively. 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 is nearing its product expiry and therefore is no longer expected to be sold. Excluding the one-time inventory obsolescence charge, gross margin for the first nine months of 2014 would have been 74%. 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 Milestone Revenue. During the first nine months of 2014, we recognized $300,000 of Lymphoseek milestone revenue from a non-refundable upfront milestone payment received by the Company related to the recent Lymphoseek distribution agreement for China for which the Company has no future obligations. No Lymphoseek milestone revenue was recognized during the first nine months of 2013.

Grant and Other Revenue. During the first nine months of 2014, we recognized $1.0 million of grant revenue as compared to $324,000 in the first nine months of 2013, primarily related to SBIR grants from the NIH supporting NAV4694 and NAV1800 development. The net increase was primarily due to higher NAV4694 grants offset by lower NAV1800 and Lymphoseek grants. Grant and other revenue for the first nine months of 2014 also included revenue related to services provided to R-NAV for Manocept development.

Research and Development Expenses. Research and development expenses increased $202,000, or 1%, to $14.5 million during the first nine months of 2014 from $14.3 million during the same period in 2013. The increase was primarily due to net increases in drug project expenses related to (i) increased NAV5001 development costs of $459,000 including increased clinical trial costs, manufacturing-related activities, and regulatory costs, and (ii) increased Manocept platform development costs of $133,000; offset by (iii) decreased Lymphoseek development costs of $272,000. The increase in research and development drug project expenses was offset by decreases in compensation including incentive-based awards and other expenses related to net decreased headcount related to the second quarter 2014 reduction in force.

Selling, General and Administrative Expenses. Selling, general and administrative expenses remained steady at $11.5 million during the first nine months of 2014 and 2013. Decreases in investor relations and out-of-pocket marketing costs related to the commercial launch of Lymphoseek, coupled with decreased compensation related to the second quarter 2014 reduction in force, were offset by expenses related to the separation of our former CEO, Dr. Mark Pykett, coupled with increased professional fees, medical education costs to support Lymphoseek, symposia and industry association support expenses, and facilities transition, travel and other headcount-related costs.

Other Income (Expense). Other expense, net, was $5.7 million during the first nine months of 2014 as compared to $3.6 million during the same period in 2013. Interest expense increased $974,000 to $2.8 million during the first nine months of 2014 from $1.8 million for the same period in 2013, primarily due to interest related to the Oxford and GECC/Midcap Notes in 2014, offset by interest related to the Hercules Note and Platinum credit facility in 2013. Of this interest expense, $638,000 and $502,000 in the first nine months of 2014 and 2013, respectively, was non-cash in nature related to the amortization of debt issuance costs and non-cash debt discounts related to the Oxford, GECC/MidCap, and Hercules Notes. During the first nine months of 2014, we recorded a loss on extinguishment of debt of $2.6 million related to paying off the balance of the GECC/MidCap Note. During the first nine months of 2013, we recorded losses on extinguishment of debt of $943,000 related to modification of the Platinum credit facility and $429,000 upon paying off the balance of the Hercules Note. For the first nine months of 2014, we recorded non-cash expense of $109,000 related to changes in the estimated fair value of financial instruments as compared to $377,000 during the same period in 2013. During the first nine months of 2014, we recorded non-cash expense from our equity in the loss of R-NAV of $262,000.

Liquidity and Capital Resources

Cash balances decreased to $10.4 million at September 30, 2014 from $32.9 million at December 31, 2013. The net decrease was primarily due to cash used to fund our operations, mainly for research and development activities, of $24.3 million, purchases of equipment of $1.1 million, and an investment in R-NAV of $333,000, offset by a net increase of $3.2 million related to the commencement of the Oxford Notes and the extinguishment of the GECC/Midcap Notes. The current ratio decreased to 1.7:1 as of September 30, 2014 from 3.3:1 December 31, 2013.

Operating Activities. Cash used in operations decreased $156,000 to $24.3 million during the first nine months of 2014 compared to $24.5 million used during the same period in 2013.

Accounts receivable increased to $1.5 million at September 30, 2014 from $1.2 million at December 31, 2013, primarily due to increased receivables due from Cardinal Health resulting from the increase in sales of Lymphoseek, offset by decreased amounts due from the landlord of our Dublin office space for tenant improvements.

Inventory levels decreased to $1.1 million at September 30, 2014 from $2.2 million at December 31, 2013, primarily due to a reserve for inventory obsolescence due to changes in our projections of the probability of future commercial use for the specific lot reserved, coupled with finished goods inventory sold and materials inventory consumed for product testing and development purposes. We expect inventory levels to increase over the remainder of 2014 as we produce additional Lymphoseek inventory to meet increasing demand.

Accounts payable remained steady at $2.4 million at September 30, 2014 and December 31, 2013. Accrued liabilities and other current liabilities decreased to $3.2 million at September 30, 2014 from $4.8 million at December 31, 2013, primarily due to decreased accruals of NAV4694 development costs. Our payable and accrual balances will continue to fluctuate but will likely decrease overall as we decrease our level of development activity related to NAV4694, NAV5001, NAV1800, and other potential product candidates following our second quarter 2014 realignment of priorities, offset by planned increases in development activity related to the Manocept platform and commercial activity related to Lymphoseek.

Investing Activities. Investing activities used $1.5 million during the first nine months of 2014 compared to using $791,000 during the same period in 2013. Capital expenditures of $1.1 million during the first nine months of 2014 were primarily for leasehold improvements, office furniture and NAV4694 production equipment. Capital expenditures of $763,000 during the first nine months of 2013 were primarily for equipment to be used in the production of NAV4694 and Lymphoseek, software, and computers. We expect our overall capital expenditures for the remainder of 2014 will be lower than for the same period in 2013.

Financing Activities. Financing activities provided $3.2 million during the first nine months of 2014 compared to $60.8 million provided during the same period in 2013. 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 payment of the principal and fees related to the extinguishment of the GECC/Midcap Notes of $26.7 million. The $60.8 million provided by financing activities in the first nine months of 2013 consisted primarily of proceeds from the issuance of common stock of $41.3 million and proceeds from notes payable of $29.0 million, offset by principal payments on our notes payable of $6.0 million, payment of common stock issuance costs of $1.7 million, payment of debt issuance costs of $1.2 million, and payment of minimum tax withholdings related to stock-based compensation of $659,000.

Investment in R-NAV, LLC

In July 2014, Navidea announced that it formed a joint enterprise with Essex Woodlands-backed Rheumco, LLC, to develop and commercialize radiolabeled diagnostic and therapeutic products for rheumatologic and arthritic diseases. The joint enterprise, called R-NAV, will combine Navidea's proprietary Manocept CD206 macrophage targeting platform and Rheumco's proprietary Tin-117m radioisotope technology to focus on leveraging the platforms across several indications with high unmet medical need:

R-NAV Subsidiary 1A:	Detection of RA initially using Tc-99m tilmanocept, commercially known as Lymphoseek,
R-NAV Subsidiary 1B:	Combination of the Manocept platform with Tin-117m for detection and treatment of RA,
R-NAV Subsidiary 2:	Detection and treatment of human and veterinary osteoarthritis (OA) using the Tin-117m technology, and
R-NAV Subsidiary 3:	Treatment of pediatric hemophilic arthropathy (PHA), a rare rheumatologic condition.

Both Rheumco and Navidea have contributed licenses for intellectual property and technology to R-NAV in exchange for common units in R-NAV. Each of the licenses has grant-back provisions with respect to inventions and other intellectual property developed in these programs outside of the exclusive fields of use specified in the license.

R-NAV was initially capitalized through a $4.0 million investment from Infinity Capital III, of Houston-based McRay Money Management, and other third-party private investors, and the technology contributions from Rheumco and Navidea. Navidea has committed an additional $1.0 million investment to be paid over three years, with $333,334 in cash contributed at inception and a promissory note in the principal amount of $666,666, payable in two equal installments on the first and second anniversaries of the transaction. The note will bear interest at the applicable federal rate, currently 0.31% per annum. In exchange for its capital and in-kind investment, the Company received 1,000,000 Series A preferred units of R-NAV (Series A Units). The Company will recognize an additional 500,000 Series A Units for management and technical services associated with the programs described above to be performed by the Company for R-NAV pursuant to a services agreement. The Series A Units are convertible into common units at the option of the holder for a conversion price of $1 per unit, subject to broad-based weighted average anti-dilution rights.

Navidea initially owns approximately 34% of the combined entity. Joint oversight of R-NAV is shared between Navidea, Rheumco, Infinity Capital, and the other investors. Navidea has three-year call options to acquire, at its sole discretion, all of the equity of Subsidiary 1A for $10.5 million prior to the launch of a Phase 3 clinical trial for its development program, and all of the equity of Subsidiary 1B at fair value upon completion of radiochemistry and biodistribution studies for its development program.

Oxford Debt

In March 2014, we executed a Loan and Security Agreement (the Oxford Loan Agreement) with Oxford Finance, LLC (Oxford), providing for a loan to the Company of $30 million. Pursuant to the Oxford Loan Agreement, we issued Oxford: (1) Term Notes in the aggregate principal amount of $30,000,000, bearing interest at 8.5% (the Oxford Notes), and (2) Series KK warrants to purchase an aggregate of 391,000 shares of our common stock at an exercise price of $1.918 per share, expiring in March 2021 (the Series KK warrants). We will make monthly payments of interest only commencing on April 1, 2014, and continuing on the first calendar day of each successive month thereafter through and including the first calendar day of the month immediately preceding April 1, 2015 (the Amortization Date, which may be extended to April 1, 2016, and again to April 1, 2017, if the Company achieves certain milestones associated with the Company's Lymphoseek product). Commencing on the Amortization Date, and continuing on the first calendar day of each month thereafter, the Company will make consecutive equal monthly payments of principal and interest, in arrears, to the lenders then party to the Oxford Loan Agreement based on a repayment schedule of 48 months if the Amortization Date is April 1, 2015, 36 months if the Amortization Date is April 1, 2016, and 24 months if the Amortization Date is April 1, 2017. Based on our current outlook, we expect to begin making principal payments on April 1, 2015. All unpaid principal, and accrued and unpaid interest, with respect to the Oxford Notes is due and payable in full on March 1, 2019. We will also make a final payment to the lenders in an aggregate amount equal to the original principal amount of the loan multiplied by 7.95% if the Amortization Date is April 1, 2015; 8.95% if the Amortization Date is extended to April 1, 2016; or 9.95% if the Amortization Date is extended to April 1, 2017. The Oxford Notes are collateralized by a security interest in substantially all of the Company's assets except for intellectual property, as to which the security interest is in rights to income or proceeds from the sale or licensing thereof. The Oxford Loan Agreement requires that the Company adhere to certain affirmative and negative covenants, including, without limitation, financial reporting requirements and a prohibition against the incurrence of indebtedness, or creation of additional liens, other than as specifically permitted by the terms of the Oxford Loan Agreement. As of September 30, 2014, the outstanding principal balance of the Oxford Loan Agreement was $30.0 million, and we were in compliance with all covenants of the Oxford Loan Agreement.

In July 2014, in connection with entering into the R-NAV joint enterprise, we entered into an amendment to the Oxford Loan Agreement that amended certain covenants to permit our investment in R-NAV, and R-NAV entered into a Subordination Agreement with Oxford to subordinate our indebtedness to R-NAV to our obligations under the Oxford Loan Agreement.

GECC/MidCap Debt

Also in March 2014, in connection with the consummation of the Oxford Loan Agreement, we repaid all amounts outstanding under the General Electric Capital Corporation (GECC) and MidCap Financial SBIC, LP (MidCap) Notes for a payoff amount of $26.7 million, which included payments of $500,000 as a pre-payment fee and $1,000,000 as an end-of-term final payment fee.

Platinum Credit Facility

In March 2014, in connection with entering into the Oxford Loan Agreement, we entered into a second amendment to the Platinum-Montaur Life Sciences, LLC (Platinum) Loan Agreement (the Second Platinum Amendment). Concurrent with the execution of the Second Platinum Amendment, the Company delivered an Amended and Restated Promissory Note (the Second Amended Platinum Note) to Platinum, which amended and restated the First Amended Platinum Note. The Second Amended Platinum Note adjusted the interest rate to the greater of (i) the United States prime rate as reported in The Wall Street Journal plus 6.75%, (ii) 10.0%, and (iii) the highest rate of interest then payable by the Company pursuant to the Oxford Loan Agreement plus 0.125%. Navidea, Platinum, and Oxford also entered into a Subordination Agreement, providing for subordination of the Company's indebtedness under the

Platinum Loan Agreement to the Company's indebtedness under the Oxford Loan Agreement, among other customary terms and conditions. As of September 30, 2014, the remaining outstanding principal balance of the Second Amended Platinum Note was approximately $3.2 million, with $31.8 million still contractually available under the credit facility.

Summary

Our future liquidity and capital requirements will depend on a number of factors, including our ability to complete the development and commercialization of new products, our ability to achieve market acceptance of our 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 additional pipeline development opportunities and 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 involves reducing our near-term support for our two neurological product candidates, NAV4694 and NAV5001, as we seek to secure a development partner for these programs. The Company is also working to establish new sources of non-dilutive funding, including collaborations 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 recently announced R-NAV venture, which we believe may further expand the Company's pipeline but which require less near-term funding from Navidea than the two ongoing Phase 3 neurological development programs. 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.

We believe that our current cash balance, our credit facility with Platinum, our projected revenue derived from U.S. sales of Lymphoseek, our ability to control expenses, the potential for partnership funding, the potential to access debt or royalty instruments, and the potential to access capital markets through our shelf registration (though we have no current intention to raise additional equity capital using the shelf registration), provide us with adequate financial resources to continue to fund our business plan for the foreseeable future. However, we cannot assure you that Lymphoseek will generate our expected levels of sales and cash flow. We will continue to evaluate our time lines, strategic needs, and balance sheet requirements. We cannot assure you that if we attempt to raise additional capital through debt, royalty, equity or otherwise, we will be successful in doing so on terms acceptable to the Company, or at all. We also cannot assure you that we will be able to gain access and/or be able to execute on securing new development opportunities, successfully obtain regulatory approval for and commercialize new products, achieve significant product revenues from our products, or achieve or sustain profitability in the future.

Recent Accounting Developments

In May 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2014-09, Revenue from Contracts with Customers, which supersedes nearly all existing revenue recognition guidance under U.S. GAAP. The core principle of ASU 2014-09 is built on the contract between a vendor and a customer for the provision of goods and services. It attempts to depict the exchange of rights and obligations between the parties in the pattern of revenue recognition based on the consideration to which the vendor is entitled. To accomplish this objective, ASU 2014-09 requires five basic steps: (i) identify the contract with the customer, (ii) identify the performance obligations in the contract, (iii) determine the transaction price, (iv) allocate the transaction price to the performance obligations in the contract, (v) recognize revenue when (or as) the entity satisfies a performance obligation. Entities will generally be required to make more estimates and use more judgment than under current guidance, which will be highlighted for users through increased disclosure requirements. ASU 2014-09 is effective for public entities for annual periods beginning after December 15, 2016, including interim periods therein. Three basic transition methods are available - full retrospective, retrospective with certain practical expedients, and a cumulative effect approach. Early adoption is prohibited. We are currently evaluating the impact of our pending adoption of ASU 2014-09 on our consolidated financial statements and have not yet determined the method by which we will adopt the standard in 2017.

In June 2014, the FASB issued ASU No. 2014-12, Compensation-Stock Compensation. ASU 2014-12 requires that a performance target included in a share-based payment award that affects vesting and that could be achieved after the requisite service period be treated as a performance condition. Therefore, under the existing stock compensation guidance in Topic 718, the performance target should not be reflected in estimating the grant-date fair value of the award. Compensation cost should be recognized in the period in which it becomes probable that the performance target will be achieved and should represent the compensation cost attributable to the period(s) for which the requisite service has already been rendered. If the performance target becomes probable of being achieved before the end of the requisite service period, the remaining unrecognized compensation cost should be recognized prospectively over the remaining requisite service period. The total amount of compensation cost recognized during and after the requisite service period should reflect the number of awards that are expected to vest and should be adjusted to reflect those awards that ultimately vest. The requisite service period ends when the employee can cease rendering service and still be eligible to vest in the award if the performance target is achieved. ASU 2014-12 is effective for annual periods beginning after December 15, 2015, including interim periods therein. Earlier adoption is permitted. Entities may apply the amendments in ASU 2014-12 either (a) prospectively to all awards granted or modified after the effective date or (b) retrospectively to all awards with performance targets that are outstanding as of the beginning of the earliest annual period presented in the financial statements and to all new or modified awards thereafter. If retrospective transition is adopted, the cumulative effect of applying ASU 2014-12 as of the beginning of the earliest annual period presented in the financial statements should be recognized as an adjustment to the opening retained earnings balance at that date.

Additionally, if retrospective transition is adopted, an entity may use hindsight in measuring and recognizing the compensation cost. We do not expect the adoption of ASU 2014-12 to have a material effect on our consolidated financial statements.

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

Critical Accounting Policies

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

Revenue Recognition. We currently generate revenue primarily from sales of Lymphoseek. Our standard shipping terms are FOB shipping point, and title and risk of loss passes to the customer upon delivery to a carrier for shipment from Cardinal Health's national distribution center to another point of destination. We generally recognize sales revenue related to sales of our products when the products are shipped. Our customers have no right to return products purchased in the ordinary course of business.

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

We also earn revenue related to milestones as defined in our distribution agreements. Such revenue is recognized when the milestones are achieved with no future obligations and payments under the agreements become contractually due.

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.

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

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk. As of September 30, 2014, our $10.4 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, 2014, the interest rate on certain of our debt obligations was based on the U.S. prime rate. Based on the amount of our variable-rate borrowings at September 30, 2014, which totaled approximately $3.2 million, an immediate one percentage point increase in the U.S. prime rate would increase our annual interest expense by approximately $32,000. This estimate assumes that the amount of variable rate borrowings remains constant for an annual period and that the interest rate change occurs at the beginning of the period. Because our debt obligations are currently subject to the minimum interest rates defined in the loan agreements, a decrease in the U.S. prime rate would not affect our annual interest expense.

Foreign Currency Exchange Rate Risk. We do not currently have material foreign currency exposure related to our assets as the majority are denominated in U.S. currency and our foreign-currency based transaction exchange risk is not material. For the nine months ended September 30, 2014 and 2013, we recorded foreign currency transaction gains (losses) of approximately $49,000 and $(22,000), 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, the majority of which are defined and fixed by the warrant agreement, including the price of Company stock. As of September 30, 2014, we had approximately $7.7 million of derivative liabilities recorded on our balance sheet related to outstanding Series JJ warrants. Due to the fixed inputs defined by the warrant agreement, a hypothetical 50% change in our stock price would have no effect on the value of our derivative liabilities.

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, 2014. 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, 2014, 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.

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PART II - OTHER INFORMATION

Item 1A. Risk Factors

There have been no material changes to the Company's risk factors as previously reported in the Company's Annual Report on Form 10-K for the year ended December 31, 2013, filed with the SEC on March 14, 2014.

Item 6. Exhibits

10.1	Form of Stock Option Agreement under the Navidea Biopharmaceuticals, Inc. 2014 Stock Incentive Plan.*
10.2	Form of Restricted Stock Award and Agreement under the Navidea Biopharmaceuticals, Inc. 2014 Stock Incentive Plan.*
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*
32.1	Certification of Chief Executive Officer of Periodic Financial Reports pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350.**
32.2	Certification of Chief Financial Officer of Periodic Financial Reports pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350.**
101.INS	XBRL Instance Document*
101.SCH	XBRL Taxonomy Extension Schema Document*
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document*
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document*
101.LAB	XBRL Taxonomy Extension Label Linkbase Document*
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document*

* Filed herewith.
** Furnished herewith.

Items 1, 2, 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 10, 2014

By: /s/ Ricardo J. Gonzalez

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

By: /s/ Brent L. Larson

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

INDEX TO EXHIBITS

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