NAVIDEA BIOPHARMACEUTICALS, INC.
Form 10-Q
November 12, 2013

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, 2013

.. 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.)
425 Metro Place North, Suite 450, Dublin, Ohio	43017-1367
(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: 134,345,483 shares of common stock, par value $.001 per share (as of the close of business on November 5, 2013).

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PART I – FINANCIAL INFORMATION

Item 1. Financial Statements

Navidea Biopharmaceuticals, Inc. and Subsidiaries
Consolidated Balance Sheets

ASSETS	September 30, 2013 (unaudited)	December 31, 2012
Current assets:		
Cash	$44,632,604	$9,118,564
Accounts receivable	157,826	17,605
Inventory	2,042,784	297,500
Prepaid expenses and other	790,156	1,183,714
Total current assets	47,623,370	10,617,383
Property and equipment	2,779,659	2,026,895
Less accumulated depreciation and amortization	1,400,559	1,092,317
	1,379,100	934,578
Patents and trademarks	143,370	115,053
Less accumulated amortization	25,523	22,571
	117,847	92,482
Deferred debt issuance costs and other	816,391	327,954
Total assets	$49,936,708	$11,972,397

Continued

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

LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)	September 30, 2013 (unaudited)	December 31, 2012
Current liabilities:		
Accounts payable	$1,704,945	$1,417,463
Accrued liabilities and other	2,908,964	2,016,358
Notes payable, current, net of discounts of $727,265 and $202,287, respectively	1,692,091	2,756,718
Total current liabilities	6,306,000	6,190,539
Notes payable, net of discounts of $1,043,529 and $93,038, respectively	26,087,219	6,930,112
Derivative liabilities	7,675,446	—
Other liabilities	1,005,310	257,122
Total liabilities	41,073,975	13,377,773
Commitments and contingencies		
Stockholders' equity (deficit):		
Preferred stock; $.001 par value; 5,000,000 shares authorized; 8,012 and 6,938 Series B shares issued and outstanding at September 30, 2013 and December 31, 2012, respectively	8	7
Common stock; $.001 par value; 200,000,000 shares authorized; 134,345,483 and 113,018,772 shares issued and outstanding at September 30, 2013 and December 31, 2012, respectively	134,345	113,019
Additional paid-in capital	312,233,801	273,039,442
Accumulated deficit	(303,505,421)	(274,557,844)
Total stockholders' equity (deficit)	8,862,733	(1,405,376)
Total liabilities and stockholders' equity (deficit)	$49,936,708	$11,972,397

See accompanying notes to consolidated financial statements (unaudited).

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

	Three Months Ended September 30, 2013		Nine Months Ended September 30, 2013	
	2013	2012	2013	2012
Revenue:				
Net sales	$143,799	$—	$271,620	$—
Grant and other revenue	256,575	—	324,031	71,931
Total revenue	400,374	—	595,651	71,931
Cost of goods sold	75,422	—	180,860	—
Gross profit	324,952	—	414,791	71,931
Operating expenses:				
Research and development	6,278,459	6,127,546	14,295,049	12,547,373
Selling, general and administrative	3,971,172	2,941,851	11,505,099	8,487,318
Total operating expenses	10,249,631	9,069,397	25,800,148	21,034,691
Loss from operations	(9,924,679)	(9,069,397)	(25,385,357)	(20,962,760)
Other income (expense):				
Interest income	5,623	4,947	9,082	22,850
Interest expense	(976,226)	(315,262)	(1,804,576)	(930,338)
Loss on extinguishment of debt	—	—	(1,372,266)	—
Change in fair value of financial instruments	(377,474)	283,731	(377,474)	6,842
Other, net	(33,451)	(2,619)	(16,986)	(59,088)
Total other expense, net	(1,381,528)	(29,203)	(3,562,220)	(959,734)
Net loss	(11,306,207)	(9,098,600)	(28,947,577)	(21,922,494)
Preferred stock dividends	—	(25,000)	—	(75,000)
Net loss attributable to common stockholders	$(11,306,207)	$(9,123,600)	$(28,947,577)	$(21,997,494)
Loss per common share (basic and diluted)	$(0.09)	$(0.09)	$(0.25)	$(0.23)
Weighted average shares outstanding (basic and diluted)	121,117,562	102,332,983	117,740,754	97,042,832

See accompanying notes to consolidated financial statements (unaudited).

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

	Preferred Stock		Common Stock		Additional Paid-In	Accumulated	
	Shares	Amount	Shares	Amount	Capital	Deficit	Total
Balance, December 31, 2012	6,938	$7	113,018,772	$113,019	$273,039,442	$(274,557,844)	$(1,405,376)
Issued stock in connection with public offerings, net	—	—	14,205,770	14,205	38,118,273	—	38,132,478
Issued stock upon exercise of stock options, net	—	—	39,649	40	(9,201)	—	(9,161)
Issued restricted stock	—	—	61,250	61	—	—	61
Canceled stock to pay employee tax obligations	—	—	(194,077)	(194)	(610,362)	—	(610,556)
Canceled forfeited restricted stock	—	—	(29,250)	(29)	—	—	(29)
Issued stock upon exercise of warrants	2,365	2	3,000,000	3,000	6,158,330	—	6,161,332
Issued stock to 401(k) plan	—	—	22,126	22	66,755	—	66,777
Conversion of Series B preferred stock to common stock	(1,291)	(1)	4,221,243	4,221	(4,220)	—	—
Issued warrants in connection with debt issuance	—	—	—	—	967,115	—	967,115
Issued warrants in connection with public offering	—	—	—	—	(7,686,046)	—	(7,686,046)
Stock compensation expense	—	—	—	—	2,193,715	—	2,193,715
Net loss	—	—	—	—	—	(28,947,577)	(28,947,577)
Balance, September 30, 2013	8,012	$8	134,345,483	$134,345	$312,233,801	$(303,505,421)	$8,862,733

See accompanying notes to consolidated financial statements (unaudited).

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

	Nine Months Ended September 30, 2013	
	2013	2012
Cash flows from operating activities:		
Net loss	$(28,947,577)	$(21,922,494)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	320,139	139,424
Loss on disposal and abandonment of assets	1,160	—
Stock compensation expense	2,193,715	1,722,127
Loss on extinguishment of debt	1,372,266	—
Amortization of debt discount and issuance costs	501,600	406,982
Change in fair value of financial instruments	377,474	(6,842)
Issued stock to 401(k) plan	66,777	50,272
Issuance of common stock for payment of sublicense fee	—	1,146,000
Changes in operating assets and liabilities:		
Accounts receivable	(49,263)	2,189
Inventory	(1,745,284)	180,549
Prepaid expenses and other assets	302,600	231,618
Accounts payable	287,312	1,289,615
Accrued liabilities and other liabilities	862,470	155,864
Net cash used in operating activities	(24,456,611)	(16,604,696)
Cash flows from investing activities:		
Purchases of equipment	(762,869)	(617,699)
Patent and trademark costs	(28,317)	(5,969)
Net cash used in investing activities	(791,186)	(623,668)
Cash flows from financing activities:		
Proceeds from issuance of common stock	41,303,738	758,695
Payment of common stock issuance costs	(1,717,064)	—
Payment of tax withholdings related to stock-based compensation	(659,018)	(8,765)
Payment for common stock repurchased from executives	—	(100,875)
Payment of preferred stock dividends	—	(75,000)
Proceeds from notes payable	29,000,000	—
Payment of debt issuance costs	(1,177,293)	(153,949)
Principal payments on notes payable	(5,982,156)	(620,480)
Payments under capital leases	(6,370)	(4,096)
Net cash provided by (used in) financing activities	60,761,837	(204,470)
Net increase (decrease) in cash	35,514,040	(17,432,834)
Cash, beginning of period	9,118,564	28,644,004
Cash, end of period	$44,632,604	$11,211,170

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, 2013 and for the three-month and nine-month periods ended September 30, 2013 and 2012 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, 2013 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, 2012, which were included as part of our Annual Report on Form 10-K.

Our consolidated financial statements include the accounts of Navidea, our wholly owned subsidiaries, Navidea Biopharmaceuticals Limited and Cardiosonix Ltd. (Cardiosonix), and our majority owned subsidiary, Cira Biosciences, Inc. (Cira Bio). 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, 2013 and December 31, 2012 consists of the face amount of the notes less unamortized discounts. See Note 6. At September 30, 2013, certain elements of our debt were also required to be recorded at fair value, which includes the fair value attributable to an embedded conversion option. The estimated fair value of our debt was calculated using a discounted cash flow analysis as well as a Monte Carlo simulation in 2013. These valuation methods include Level 3 inputs such as the estimated current market interest rate for similar instruments with similar creditworthiness. At September 30, 2013, the fair value of our notes payable is approximately $30.3 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, 2013 include volatility, risk-free rate and expected dividends. In addition, we considered non-performance risk and determined that such risk is minimal. Unrealized gains and losses on the derivatives are classified in other expenses as a change in the fair value of financial instruments in the statements of operations. See Note 7.

c. Revenue Recognition: We currently generate revenue 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 generate additional revenue from grants to support various product development initiatives. We generally recognize grant revenue when expenses reimbursable under the grants have been incurred and payments under the grants become contractually due. We also recognize revenue from the reimbursement by our partners of certain expenditures for which the Company has principal responsibility.

d. Recent Accounting Developments: In February 2013, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2013-2, Comprehensive Income (Topic 220). ASU 2013-2 provides entities with two basic options for reporting the effect of significant reclassifications – either (1) on the face of the statement where net income is presented or (2) as a separate footnote disclosure. Public entities will report reclassifications in both annual and interim periods. Under option 1, the effect of significant reclassifications is presented parenthetically by component of other comprehensive income (OCI) on the respective line items of net income. Entities must also parenthetically report the aggregate tax effect of reclassifications in the income tax expense (benefit) line item. Under option 2, the significant amounts of each component of OCI must be presented in a single footnote. ASU 2013-2 is effective prospectively for reporting periods beginning after December 15, 2012. ASU 2013-2 did not have an effect on our consolidated financial statements.

In July 2013, the FASB issued ASU No. 2013-11, Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists (ASU 2013-11). ASU 2013-11 requires an entity to present an unrecognized tax benefit in the financial statements as a reduction to a deferred tax asset for a net operating loss (NOL) carryforward, a similar tax loss, or a tax credit carryforward except when: (1) a NOL carryforward, a similar tax loss, or a tax credit carryforward is not available as of the reporting date under the governing tax law to settle taxes that would result from the disallowance of the tax position; or (2) the entity does not intend to use the deferred tax asset for this purpose (provided that the tax law permits a choice). If either of these conditions exists, an entity should present an unrecognized tax benefit in the financial statements as a liability and should not net the unrecognized tax benefit with a deferred tax asset. ASU 2013-11 does not affect the recognition or measurement of uncertain tax positions under ASC 740. ASU 2013-11 is effective for fiscal years, and interim periods within those years, beginning after December 15, 2013. ASU 2013-11 should be applied prospectively to all unrecognized tax benefits that exist at the effective date. Retrospective application is permitted. We do not expect ASU 2013-11 to have an impact on our consolidated financial statements.

2. Fair Value Hierarchy

Under certain circumstances, beginning in the second quarter of 2013, Platinum-Montaur Life Sciences, Inc. (Montaur) has the right to convert all or any portion of the unpaid principal or unpaid interest accrued on any future draws under the Montaur credit facility. Montaur's option to convert future 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 sheet. The estimated fair value of the Montaur notes payable is $4.6 million at September 30, 2013, and will be measured on a recurring basis. See Note 6.

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 derivative liabilities with an estimated fair value of $7.7 million on the date the warrants were issued. The estimated fair value remained at $7.7 million as of September 30, 2013, and will be measured on a recurring basis. See Note 7.

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, 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 September 30, 2013
Montaur notes payable	$—	$—	$4,550,104	$4,550,104
Derivative liabilities related to warrants	—	7,675,446	—	7,675,446

There were no financial assets or liabilities measured at fair value on a recurring basis as of December 31, 2012. There were no Level 1 liabilities outstanding at any time during the three-month or nine-month periods ended September 30, 2013 and 2012. There were no transfers in or out of our Level 2 liabilities during the three-month or nine-month periods ended September 30, 2013 or 2012.

3. Stock-Based Compensation

At September 30, 2013, we have instruments outstanding under two stock-based compensation plans; the 1996 Stock Incentive Plan (the 1996 Plan) and the Fourth Amended and Restated 2002 Stock Incentive Plan (the 2002 Plan). Currently, under the 2002 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 and 12 million shares, respectively. Although instruments are still outstanding under the 1996 Plan, the plan has expired and no new grants may be made from it. Under both plans, the exercise price of each option is greater than or equal to the closing market price of our common stock on the date of the grant.

Stock options granted under the 1996 Plan and the 2002 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 statement 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.

For the three-month periods ended September 30, 2013 and 2012, our total stock-based compensation expense was approximately $772,000 and $588,000, respectively. For the nine-month periods ended September 30, 2013 and 2012, our total stock-based compensation expense was approximately $2.2 million and $1.7 million, respectively. We have not recorded any income tax benefit related to stock-based compensation in either the three-month or nine-month periods ended September 30, 2013 and 2012.

A summary of the status of our stock options as of September 30, 2013, and changes during the nine-month period then ended, is presented below:

	Nine Months Ended September 30, 2013			
	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value
Outstanding at beginning of period	3,412,777	$2.01		
Granted	1,705,725	3.06		
Exercised	(60,000)	0.84		
Canceled and Forfeited	(105,150)	2.97		
Expired	(30,000)	0.19		
Outstanding at end of period	4,923,352	$2.36	7.3 years	$2,976,564
Exercisable at end of period	2,128,540	$1.49	5.1 years	$2,796,288

Following a review undertaken by the Company's Board of Directors and senior management in June 2013, the Company determined that the Board had inadvertently granted stock awards in February 2012 to the Company's Chief Executive Officer, Mark J. Pykett, in excess of the amount then authorized under the 2002 Plan. Consequently, the Board canceled options to purchase 50,000 shares of the Company's common stock issued to Dr. Pykett (the amount by which the grants to Dr. Pykett in February 2012 exceeded the 2002 Plan's share limitation), and Dr. Pykett agreed to the cancellation.

A summary of the status of our unvested restricted stock as of September 30, 2013, and changes during the nine-month period then ended, is presented below:

	Nine Months Ended September 30, 2013	
	Number of Shares	Weighted Average Grant-Date Fair Value
Unvested at beginning of period	1,335,000	$2.28
Granted	61,250	2.91
Vested	(745,000)	1.86
Forfeited	(29,250)	4.23
Expired	—	—
Unvested at end of period	622,000	$2.75

In February 2013, 100,000 shares of restricted stock with an aggregate fair value of $308,000 vested as scheduled according to the terms of a restricted stock agreement. In March 2013, the Company received FDA approval to market Lymphoseek®. As a result of the Lymphoseek approval, 560,000 shares of restricted stock vested with an aggregate fair value of $1.8 million.

In April 2013, 85,000 shares of restricted stock held by non-employee directors with an aggregate fair value of $224,000 vested as scheduled according to the terms of the restricted stock agreements. In July 2013, 29,250 shares of restricted stock with an aggregate fair value of $48,000 were forfeited as a result of a non-employee director departing from the board.

As of September 30, 2013, there was approximately $2.8 million of total unrecognized compensation expense related to unvested stock-based awards, which we expect to recognize over remaining weighted average vesting terms of 2.0 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.

The following table sets forth the calculation of basic and diluted earnings (loss) per share for the three-month and nine-month periods ended September 30, 2013 and 2012:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Net loss	$(11,306,207)	$(9,098,600)	$(28,947,577)	$(21,922,494)
Preferred stock dividends	—	(25,000)	—	(75,000)
Net loss attributable to common stockholders	$(11,306,207)	$(9,123,600)	$(28,947,577)	$(21,997,494)
Weighted average shares outstanding (basic and diluted)	121,117,562	102,332,983	117,740,754	97,042,832
Loss per common share (basic and diluted)	$(0.09)	$(0.09)	$(0.25)	$(0.23)

Earnings (loss) per common share for the three-month and nine-month periods ended September 30, 2013 and 2012 excludes the effects of 33.5 million and 45.0 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, 622,000 and 1,911,000 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, 2013 and 2012, 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, 2013 and December 31, 2012, net of reserves of $0 and $308,000, respectively, are as follows:

	September 30, 2013	December 31, 2012
	(unaudited)	
Materials	$652,818	$297,500
Work-in-process	811,053	—
Finished goods	578,913	—
Total	$2,042,784	$297,500

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During the three-month periods ended September 30, 2013 and 2012, we wrote off $298,000 and $278,000, respectively, of previously capitalized Lymphoseek inventory due to the consumption of the Lymphoseek material for product testing purposes. During the nine-month periods ended September 30, 2013 and 2012, we wrote off $298,000 and $378,000, 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, 2012, we recorded an obsolescence reserve for $339,000 of Lymphoseek inventory due to changes in our projections of the probability of future commercial use for the specific lots previously capitalized.

6. Notes Payable

In June 2013, we executed a Loan and Security Agreement (the Loan Agreement) with General Electric Capital Corporation (GECC) and MidCap Financial SBIC, LP (MidCap), providing for a loan to the Company of $25 million. Pursuant to the Loan Agreement, we issued GECC and MidCap: (1) Term Notes in the aggregate principal amount of $25,000,000, bearing interest at 9.83%, and (2) Series HH Warrants to purchase an aggregate of 301,205 shares of our common stock at an exercise price of $2.49 per share, expiring in June 2023 (the Series HH Warrants). The Loan Agreement provides for an interest-only period beginning on June 25, 2013 and expiring on June 30, 2014. The principal and interest is to be repaid in 30 equal monthly installments, payable on the first of each month following the expiration of the interest-only period, and one final payment in an amount equal to the entire remaining principal balance of the Term Note on the maturity date. The outstanding balance of the debt is due December 23, 2016. On the date upon which the outstanding principal amount of the loan is paid in full, the Company will be required to pay a non-refundable end-of-term fee equal to 4.0% of the original principal amount of the loan. The debt is 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 Loan Agreement also specifies certain covenants including the requirement that Navidea maintains a minimum cash balance greater than six times its monthly cash burn amount and provides certain information, such as financial statements and budgets, on a periodic basis. As of September 30, 2013, the minimum cash balance required was $17.6 million, and we were in compliance with all covenants of the Loan Agreement. As of September 30, 2013, the outstanding principal balance of the GECC/MidCap Loan Agreement was $25.0 million.

The Company recorded a debt discount related to the issuance of the Series HH Warrants and other fees to the lenders totaling $1.9 million. Debt issuance costs directly attributable to the Loan Agreement, totaling $881,000, were recorded as other assets on the balance sheet on the closing date. The debt discount and debt issuance costs are being amortized as non-cash interest expense using the effective interest method over the term of the Loan Agreement. As of September 30, 2013, the balance of the debt discount was $1.8 million and the balance of the debt issuance costs was $783,000.

During the period from January 1, 2013 through June 24, 2013, we paid $1.3 million of principal payments on our note payable to Hercules Technology II, L.P. (Hercules). On June 25, 2013, the Company used a portion of the proceeds from the GECC/MidCap loan to pay the remaining $4.4 million of principal outstanding on the Hercules note, as well as a $250,000 end-of-term fee and a $66,000 early payment penalty in accordance with the terms of the Hercules note. We recorded a loss on extinguishment of the Hercules debt of $429,000, consisting of the write-off of the remaining unamortized discount of $187,000 and unamortized debt issuance costs of $176,000, as well as the early payment penalty of $66,000. During the three-month and nine-month periods ended September 30, 2012, we paid $620,000 of principal payments on the Hercules debt. As of September 30, 2013, the note payable to Hercules was no longer outstanding.

Concurrent with entering into the GECC/MidCap Loan Agreement, the Company and Montaur entered into an Amendment to the July 2012 Loan Agreement between the Company and Montaur (the Montaur Amendment). Navidea, Montaur, and GECC/MidCap also entered into a Subordination Agreement (Subordination Agreement), providing for subordination of the Company's indebtedness under the Montaur credit facility to the Company's indebtedness under the GECC/MidCap Loan Agreement, among other customary terms and conditions.

In connection with the execution of the Montaur Amendment, the Company delivered an Amended and Restated Promissory Note (the Amended Montaur Note) to Montaur, which amends and restates the original promissory note, issued to Montaur, in the principal amount of up to $35,000,000. The Amended Montaur Note also adjusts the interest rate to the greater of (a) the U.S. Prime Rate as reported in the Wall Street Journal plus 6.75%; (b) 10.0%; or (c) the highest rate of interest then payable pursuant to the GECC/MidCap Loan Agreement plus 0.125% (effective interest rate at September 30, 2013 was 10%). In addition, the Montaur Amendment grants Montaur the right, at Montaur's option, to convert all or any portion of the unpaid principal or unpaid interest accrued on any future draws (the Conversion Amount), beginning on a date two years from the date the draw was advanced, into the number of shares of Navidea's common stock computed by dividing the Conversion Amount by a conversion price equal to the lesser of (i) 90% of the lowest VWAP for the 10 trading days preceding the date of such conversion request, or (ii) the average VWAP for the 10 trading days preceding the date of such conversion request. The Montaur Amendment also provides a conversion right on the same terms with respect to the amount of any mandatory repayment due following the Company achieving $2,000,000 in cumulative revenues from sales or licensing of Lymphoseek. The conversion option applies to the Conversion Amount if the Company is prohibited from making such prepayment under the terms of the Subordination Agreement.

In accordance with current accounting standards, the Montaur Amendment was treated as an extinguishment of debt. The difference between the fair value of the new debt and the carrying value of the original Montaur loan balance was recorded as a loss on extinguishment. Montaur's option to convert future draws into common stock was determined to meet the definition of a liability. The fair value of the new debt includes the estimated fair value of the embedded conversion option, which was $943,000 on the date of issuance of the Amended Montaur Note. The net increase in the estimated fair value of the Amended Montaur Note of $388,000 was recorded as a non-cash change in fair value of financial instruments during the three and nine-month periods ended September 30, 2013. The estimated fair value of the Amended Montaur Note was $4.6 million as of September 30, 2013.

Also in connection with the Montaur Amendment, the Company and Montaur entered into a Warrant Exercise Agreement (Exercise Agreement), pursuant to which Montaur exercised its Series X Warrant and Series AA Warrant for 2,364.9 shares of the Company's Series B Convertible Preferred Stock (the Series B), which are convertible into 7,733,223 shares of our common stock in the aggregate (3,270 shares of common stock per preferred share). These warrants were exercised on a cashless basis by canceling a portion of the indebtedness outstanding under the Montaur Loan Agreement equal to $4,781,333, the aggregate exercise price of the warrants. As of September 30, 2013, the remaining outstanding principal balance of the Montaur Loan Agreement was approximately $3.2 million, with $31.8 million still available under the credit facility.

During the three-month periods ended September 30, 2013 and 2012, we recorded non-cash interest expense of $258,000 and $147,000, 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, 2013 and 2012, we recorded non-cash interest expense of $502,000 and $407,000, respectively, related to amortization of the debt discounts and deferred financing costs related to our notes payable.

7. 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.

In September 2013, we entered into a Securities Purchase Agreement with Crede for a registered direct public offering. The Series JJ warrants issued in connection with the Securities Purchase Agreement are not considered to be indexed to the Company's stock due to certain features within the warrant, and as such, the warrants are required to be classified as liabilities. As a result, the Company recorded derivative liabilities with an estimated fair value of $7.7 million on the date the warrants were issued.

During the first nine months of 2012, an outside investor exercised 20,000 Series V warrants, resulting in reclassification of $52,000 in derivative liabilities related to those warrants to additional paid-in capital.

The net effect of marking the Company's derivative liabilities to market during the three-month periods ended September 30, 2013 and 2012 resulted in net decreases in the estimated fair values of the derivative liabilities of approximately $11,000 and $284,000, respectively, which were recorded as a non-cash change in the fair value of financial instruments. The net effect of marking the Company's derivative liabilities to market during the nine-month periods ended September 30, 2013 and 2012 resulted in net decreases in the estimated fair values of the derivative liabilities of approximately $11,000 and $7,000, respectively, which were recorded as a non-cash change in fair value of financial instruments. The total estimated fair value of our derivative liabilities was $7.7 million as of September 30, 2013.

8. Equity

In February 2013, we completed a public offering of 1,542,389 shares of the Company's common stock at a price of $3.10 per share (the February 2013 Offering). The net proceeds to the Company were approximately $4.5 million after deducting expenses associated with the February 2013 Offering. In April 2013, we completed another public offering of 2,100,000 shares of the Company's common stock at a price of $2.43 per share (the April 2013 Offering). The net proceeds to the Company were approximately $4.8 million after deducting expenses associated with the April 2013 Offering. The February 2013 and April 2013 Offerings were underwritten by Ladenburg Thalmann & Co. Inc. and were made pursuant to the Company's existing effective shelf registration statement on Form S-3.

In September 2013, we entered into a Securities Purchase Agreement with Crede for a registered direct public offering of 10,563,381 shares of our common stock at a price of $2.84 per share for total gross proceeds of $30.0 million. In addition to the common stock, we issued Series JJ warrants to purchase 3,169,015 shares of our common stock at an exercise price of $3.83 per share, expiring on September 24, 2016. The net proceeds to the Company were approximately $28.8 million after deducting expenses associated with the Securities Purchase Agreement, including placement agent fees of $999,000 (3.3% of the gross proceeds). The common stock, warrants, and shares of common stock underlying the warrants were issued pursuant to the Company's existing effective shelf registration statement on Form S-3. See Note 9.

In July 2013, Montaur converted 580 shares of the Series B into 1,896,600 shares of our common stock under the terms of the Series B. In September 2013, Montaur converted 710.9 shares of the Series B into 2,324,643 shares of our common stock, also under the terms of the Series B. As of September 30, 2013, there are 8,012 shares of Series B outstanding which are convertible into 26,199,240 shares of our common stock.

9. Stock Warrants

In March 2013, Montaur exercised 3,000,000 of their Series X warrants in exchange for the issuance of 3,000,000 shares of our common stock, resulting in gross proceeds of $1,380,000.

In June 2013, pursuant to the Exercise Agreement, Montaur exercised its Series X warrant and Series AA warrant for 2,364.9 shares of the Company's Series B which are convertible into 7,733,223 shares of our common stock in the aggregate (3,270 shares of common stock per preferred share). The warrants were exercised on a cashless basis by cancelling a portion of the indebtedness outstanding under the Montaur Loan Agreement equal to $4,781,333, the aggregate exercise price of the warrants.

Also in June 2013 and pursuant to the GECC/MidCap Loan Agreement, the Company issued to GECC/MidCap Series HH warrants to purchase an aggregate of 301,205 shares of our common stock at an exercise price of $2.49 per share, expiring in June 2023.

In addition, in June 2013 we issued five-year Series II warrants to purchase 275,000 shares of our common stock at an exercise price of $3.04 per share to an investment advisory firm in connection with the GECC transaction.

In September 2013, in connection with the Crede Securities Purchase Agreement, the Company issued to Crede Series JJ warrants to purchase 3,169,015 shares of our common stock at an exercise price of $3.83 per share, expiring in September 2016. Crede can exercise the Series JJ warrants at any time at a strike price of $3.83. The warrant agreement also provides for the potential exchange of warrants into Navidea common stock for no additional consideration starting six months after the date of the Securities Purchase Agreement if, at the time of the exchange, the closing bid price for Navidea's common stock is below $3.83. The amount of shares issuable on a potential exchange is based on dividing a Black-Scholes valuation of the warrants by the closing bid price for Navidea's common stock on the date of the exchange. However, as a number of the key inputs to the Black-Scholes calculation are fixed under the terms of the warrant agreement, the Company does not expect the Black-Scholes valuation on the date of a potential exchange to vary materially from the derivative liability of $7.7 million which was reported related to the Series JJ warrants as of September 30, 2013. Based on this valuation, the Company has estimated the number of shares issuable on a potential exchange to be between 2.1 million shares (based on an exchange price of $3.83) and 3.8 million shares (based on the floor exchange price of $2.00).

At September 30, 2013, there are 4.5 million warrants outstanding to purchase our common stock. The warrants are exercisable at prices ranging from $1.97 to $3.83 per share with a weighted average exercise price of $3.39 per share.

10. 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, 2013 and December 31, 2012.

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, 2013 or December 31, 2012 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, 2013, tax years 2009-2012 remained subject to examination by federal and state tax authorities.

11. Supplemental Disclosure for Statements of Cash Flows

During the nine-month periods ended September 30, 2013 and 2012, we paid interest aggregating $1.2 million and $476,000, respectively. During the nine-month periods ended September 30, 2013 and 2012, we issued 22,126 and 17,390 shares of our common stock, respectively, as matching contributions to our 401(k) plan.

In conjunction with the GECC/MidCap Loan Agreement and the Crede Securities Purchase Agreement, we issued warrants with estimated fair values of $631,000 and $7.7 million, respectively. Additionally, $1.0 million of the debt discount fees related to the GECC/MidCap Loan Agreement have been deferred through the maturity date of the loan.

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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. Toward that end, we are currently developing five pharmaceutical platforms:

- 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 and 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 to specifically target the CD206 mannose receptor expressed on macrophages. 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 SPECT, PET, intra-operative and/or optical-fluorescence detection in a variety of disease states.
- NAV4694 is a Fluorine-18 (F-18) radiolabeled positron emission tomography (PET) imaging agent being developed as an aid in the diagnosis of patients with signs or symptoms of cognitive impairment such as Alzheimer's disease

(AD).

- NAV5001 is an Iodine-123 (I-123) radiolabeled single photon emission computed tomography (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.
- RIGScan™ is a radiolabeled monoclonal antibody being developed as a diagnostic aid for use during surgery to help surgeons locate occult or metastatic cancer, with a primary focus on colorectal cancer.

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

Product Line Overview

We believe that the future prospects for Navidea continue to improve as we execute our strategic vision to become a leader in precision diagnostics. 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, RIGScan, and our Manocept platform. We expect our overall research and development expenditures to continue to be significantly higher during 2013 as compared to 2012 due to the advances in our clinical, regulatory, and business development programs and activities, as well as personnel, contractors and consultants that support the global registration and commercialization of Lymphoseek, further development of NAV4694, NAV5001, RIGScan, and our Manocept platform. The level to which the expenditures rise will depend on the scope, requirements and timing of these strategic development initiatives in different territories around the world.

Lymphoseek

Lymphoseek is a lymph node targeting radiopharmaceutical agent intended for use in intraoperative lymphatic mapping (ILM) procedures and lymphoscintigraphy employed in the overall diagnostic assessment of certain solid tumor cancers. Lymphoseek was approved and indicated for use in lymphatic mapping for breast cancer and melanoma by the FDA in March 2013. Lymphoseek provides oncology surgeons with information useful in the identification of key predictive lymph nodes that may harbor cancer. By virtue of its targeted localization, it may also help avoid the excessive or unnecessary removal of non-cancerous lymph nodes and the surrounding tissue in patients with a variety of solid tumor cancers. Additional trials, one in head and neck cancer which was recently closed, and an ongoing trial in colorectal cancer, are anticipated to provide additional data to potentially support expansion of Lymphoseek utilization into multiple other cancer types.

In May 2013 the Company announced the commercial launch of Lymphoseek in the U.S. through a distribution agreement with Cardinal Health. Although Cardinal Health is responsible for the sale and distribution of Lymphoseek to health care professionals, we work closely with Cardinal Health in supporting marketing activities and conducting medical education programs for Lymphoseek. Although it is early in the launch, we believe we are seeing positive signs in measures of success we believe are critical when introducing a novel product such as Lymphoseek and which we believe indicate a successful initial launch.

In August 2013, we announced that the Centers for Medicare and Medicaid Services issued a Healthcare Common Procedure Coding System (HCPCS) Pass-Through “C Code” for Lymphoseek. We anticipate that the reimbursement code, which became effective on October 1, 2013, will streamline the billing and reimbursement process for hospital providers who use Lymphoseek and support its fair and equitable reimbursement. We believe this may assist in advancing utilization of Lymphoseek.

In November 2013, we announced that we have selected Norgine BV and affiliates (Norgine), a leading European specialty pharmaceutical company, as our partner for Europe and certain other territories in Africa and Austral-Asia, subject to the completion of a definitive agreement. Norgine has capabilities in regions and territories beyond Europe where we also intend to partner with them. The partnership is expected to combine Navidea’s expertise in radiopharmaceuticals, clinical development, and manufacturing with Norgine’s extensive sales and marketing organization to support a specialty pharmaceutical strategy to commercialization of Lymphoseek, particularly in Europe, that would be supportive of premium product positioning, as opposed to a commodity or a generics positioning approach. Unlike the U.S., where institutions typically rely on radiopharmaceutical products which are compounded and delivered by specialized radiopharmacy distributors such as Cardinal Health, institutions in Europe predominantly purchase non-radiolabeled material and compound the radioactive product on-site. We believe that with international partnerships to complement our position in the U.S., we will help establish Lymphoseek as a global leader in lymphatic mapping, as we are aware of no other company which has this global geographic range.

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In April 2013, the Company announced top-line results from the interim analysis of our Phase 3 clinical trial for Lymphoseek in subjects with head and neck squamous cell carcinoma (NEO3-06). Results of the pre-planned interim analysis demonstrated that Lymphoseek met the primary efficacy endpoint of accurately identifying sentinel lymph nodes (SLNs) in subjects with squamous cell carcinoma of the head, neck or mouth, as compared to the removal of all lymph nodes during multiple level nodal dissection surgery of the head and neck. Multiple level nodal dissection surgery is considered the "gold standard" in head and neck squamous cell carcinoma to determine the presence and extent of cancer spread in lymph nodes of patients with this cancer. The primary endpoint for the NEO3-06 trial was based on the number of subjects with pathology-positive lymph nodes (that is, lymph nodes found to harbor cancer) following a multiple level lymph node dissection and required a minimum of 38 subjects whose lymph nodes contained pathology-confirmed disease. Of the over 80 subjects enrolled in the NEO3-06 trial, 39 subjects were determined to have pathology-positive lymph nodes. Results demonstrated that of these 39 patients, Lymphoseek accurately identified 38, for an overall False Negative Rate (FNR) of 2.56%, which was statistically significant ($p=0.0205$) and met the statistical threshold for success of the primary endpoint. FNR is the rate of occurrence of negative test results in subjects known to have metastatic disease in the lymph nodes, for which the individual is being tested. These findings indicate that Lymphoseek accurately identified SLNs in these trial subjects, and is likely to be predictive of overall node pathology status. On the basis of the strong safety and efficacy data observed in the interim analysis, the independent Data Safety Monitoring Committee (DSMC) for the NEO3-06 trial recommended terminating enrollment and closing the study.

In September 2013, results from the NEO3-06 study conducted at The Ohio State University Comprehensive Cancer Center – James Cancer Hospital & Solove Research Institute were published in the peer-reviewed journal, JAMA Otolaryngology Head and Neck Surgery, a publication of the American Medical Association. The publication, "Use of a Novel Receptor-Targeted (CD206) Radiotracer, 99m-Tc-Tilmanocept, and SPECT/CT for Sentinel Lymph Node Detection in Oral Cavity Squamous Cell Carcinoma: Initial Institutional Report in an Ongoing Phase 3 Study," describes the experience at one of the clinical trial sites that participated in NE03-06. The results, published independently by this single clinical trial site in our larger Phase 3 NE03-06 study, corroborate data for the ability of Lymphoseek to identify sentinel lymph nodes in head and neck squamous cell carcinoma.

In October 2013, we announced additional results from the fully completed NEO3-06 study indicating that Lymphoseek also met all other pre-specified study endpoints, including sensitivity, negative predictive value (NPV) and overall accuracy relative to the pathology status of non-SLNs. Lymphoseek demonstrated a sensitivity rate of 97.6%, a NPV of 97.8%, and overall accuracy of 98.8%. No differences were observed in the ability of Lymphoseek to detect SLNs between same-day or subsequent-day surgery following Lymphoseek injection.

Moreover, multiple level nodal dissection of patients in the trial with cancer-positive lymph nodes led to an average removal of 38 lymph nodes per patient, whereas Lymphoseek on average led to the identification of approximately 4 lymph nodes. This reduction in potential lymph node removal could lead to a substantial reduction in potential morbidity for patients with head and neck cancer undergoing sentinel lymph node biopsy, as well as potentially enabling reductions in the time and cost of surgery.

The NEO3-06 clinical study was designed to demonstrate the performance of Lymphoseek in head and neck cancer as well as to potentially expand the product label for Lymphoseek as a sentinel lymph node biopsy agent after the initial marketing clearance for the product. Based on results from the NEO3-06 study, results from other studies already completed, the recommendation of the independent DSMC, and a constructive meeting with the FDA on our findings, we have officially closed the NEO3-06 study and anticipate filing a supplemental New Drug Application (NDA) for Lymphoseek in the U.S. for use in sentinel lymph node biopsy by the end of 2013.

We are currently pursuing registration of Lymphoseek in the European Union (EU). In February 2012, Navidea was advised by the European Medicines Agency (EMA) Committee for Medicinal Products for Human Use (CHMP) that

the Committee had adopted the advice of the Scientific Advice Working Party (SAWP) regarding the Lymphoseek development program and determined that Lymphoseek is eligible for a Marketing Authorization Application (MAA) submission based on clinical data accumulated from completed pivotal studies and supporting clinical literature. We submitted our MAA for Lymphoseek to the EMA in December 2012. Based on the cumulative feedback to date, we anticipate we could receive an opinion on approval from CHMP by year end. A positive opinion for approval would enable commercialization in the EU subsequent to European Commission (EC) adoption of the CHMP opinion and pricing determinations on a country-by-country basis in each member state. However, we cannot assure you that Lymphoseek will achieve regulatory approval in the EU or any 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 acts 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. 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 diagnostic agents.

In September 2013, we presented collaborative data at the Cancer Advance Conference at Harvard Medical School from the proof-of-principle imaging studies using Cy3-tilmanocept, a fluorescent-labeled agent derived from the Manocept platform, utilizing the technical principles underlying Lymphoseek. Data presented at the conference establish the feasibility of using Manocept compounds to bind to the CD206 mannose receptor and target macrophage inflammatory cells, an approach that may enable the design of novel immune cell-targeted agents for diagnosis and disease staging. These studies focused on establishing the ability of fluorescent Cy3-tilmanocept to target macrophages in two disease states which are representative of broader macrophage-associated disorders: Kaposi's Sarcoma (KS) and Tuberculosis (TB), both outside the current lymphatic mapping application. These data support the expansion of the Manocept platform into potential new indications in disorders that are mediated by, or associated with, macrophages utilizing immune-cell targeting to address unmet diagnostic needs in this emerging area. Other recognized macrophage-mediated disorders include not only KS and TB, but rheumatoid arthritis (RA), Systemic Lupus Erythematosis, atherosclerosis/vulnerable plaque, Crohn's disease and others that span clinical areas in oncology, autoimmunity, infectious diseases, cardiology, and inflammation. These data were published in a special supplement, Nature Outlook: Medical Imaging, in the 31 October 2013 issue of Nature. The supplement included a White Paper entitled "Innovations in receptor-targeted precision imaging at Navidea: Diagnosis up close and personal." The online edition also includes several peer-reviewed articles published previously by Nature Publishing Group that reinforce the principle of CD206 mannose receptor targeting using Manocept compounds to identify macrophages. 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. 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 patented Fluorine-18 labeled precision radiopharmaceutical candidate for use in the imaging and evaluation of patients with signs or symptoms of cognitive impairment such as AD. 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 thus far, NAV4694 appears to have better sensitivity and specificity in detecting beta-amyloid than other agents developed to date. 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 and better signal-to-noise ratios 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 several clinical trials in humans. Clinical studies through Phase 2 have included over 140 subjects to date. Results suggest that NAV4694 has the ability to image patients quickly and safely with high sensitivity and specificity. We are currently supporting a Phase 2 trial that we initiated in September 2012, primarily to expand the safety database for the compound, and a Phase 2b trial in subjects with mild cognitive impairment (MCI) in March 2013. In June 2013, we initiated a Phase 3 autopsy-based trial to support registration in the U.S. and the EU. The Phase 3 study utilizes a clinical trial design used by other agents that have either been submitted for, or submitted for and received, regulatory approval in the U.S. and Europe. We cannot assure you, however, that further clinical trials for this product will be successful, that it will achieve regulatory approval, or if approved, that it will achieve market acceptance.

In July 2013 at the Alzheimer's Association International Conference (AAIC), it was announced that the Australian Imaging, Biomarker & Lifestyle Flagship Study of Ageing (AIBL) plans to switch to NAV4694 for use in its comprehensive research initiative in Alzheimer's disease and MCI from a PET imaging agent for -amyloid detection that for many has remained the accepted benchmark standard for studies investigating Alzheimer's disease and differential diagnoses of dementia. The previously used compound had issues around timing, logistics and costs making its routine use challenging. Recently published results from a head-to-head study that directly compared NAV4694 to the accepted standard agent demonstrated that NAV4694 displayed nearly identical imaging characteristics of the previously used compound, and is accessible and affordable and can be reliably interpreted in a variety of clinical settings.

Also at the 2013 AAIC, researchers at the McGill Centre for Studies in Aging, Douglas Research Institute, and Montreal Neurological Institute presented results of a post-mortem brain tissue study comparing performance characteristics of NAV4694 to this gold-standard imaging agent, concluding that NAV4694 better differentiated amyloid deposition associated with AD in post-mortem brains.

In August 2013, we signed an agreement with Siemens PETNET Solutions that grants PETNET Solutions the right to manufacture NAV4694 for our clinical trials. Under the terms of the agreement, PETNET Solutions will initially manufacture NAV4694 clinical trial material at select U.S. radiopharmacies, with the possibility of expanding into additional Siemens' PETNET Solutions locations in the future.

Also in August 2013, we were awarded a Small Business Innovation Research (SBIR) grant from the National Institute On Aging (NIA) of the National Institutes of Health (NIH) in connection with our Phase 3 clinical program for NAV4694 as an aid in the differential diagnosis of Alzheimer's disease. The SBIR grant has the potential to provide up to $1.8 million in support, if fully funded, through the conclusion of the Phase 3 clinical study. Funding of $259,000 for the approved first stage of the grant is intended to provide support for initiation activities of the Phase 3 clinical program. Funding of the second stage of the grant is contingent upon meeting specific aims related to the first stage of the grant such as institutional review board approval of the Phase 3 protocol, clinical site contracting and investigator training.

In September 2013, we were awarded a SBIR grant from the NIA of the NIH in connection with the evaluation of NAV4694 as a diagnostic imaging agent that may aid physicians in identifying those individuals with MCI who are at greatest risk of progressing to AD. The grant has the potential to provide up to $2.3 million in support, if fully funded, through the conclusion of the clinical study. Funding of $152,000 for the approved first stage of the grant is intended to provide support for initiation activities of the clinical trial program. Funding of the second stage of the grant is contingent upon meeting specific aims related to the first stage of the grant such as clinical site contracting, investigator training and institutional review board approvals.

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.

NAV5001 has been administered to over 600 subjects to date. Results from clinical trials 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 typically 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 (DLB), one of the

most common forms of dementia after AD. We initiated a Phase 2b program in DLB in April 2013, commencing an investigator-initiated study. We expect to initiate a Company-sponsored Phase 2b study later in 2013. We also expect to initiate a Phase 3 trial in subjects with PD in the second half of 2013. We cannot assure you, however, that further clinical trials for this product will be successful, that it will achieve regulatory approval, or if approved, that it will achieve market acceptance.

In May 2013, we entered into an agreement with Nordion (Canada) Inc. to produce and supply NAV5001 for our late-phase clinical trials. Nordion will radiolabel the Company's drug product to form NAV5001, manage the manufacturing logistics, and ship NAV5001 to third-party clinical trial sites on behalf of Navidea.

In August 2013, we reached agreement with the FDA for two special protocol assessments (SPAs) for the Company's pivotal Phase 3 program with NAV5001 as an aid in the differential diagnosis of Parkinsonian Syndromes from non-Parkinsonian tremor. The SPAs are written agreements between the Company, as the program's sponsor, and the FDA regarding the design, endpoints and statistical analysis for the two pivotal Phase 3 clinical trials to be used in support of a potential NAV5001 NDA. The Company is actively preparing for the initiation of the pivotal Phase 3 trials later this year. The international, open-label, pivotal NAV5001 Phase 3 program consists of two similar clinical trials that will run in parallel and enroll approximately 550 total subjects who exhibit early stage tremor. Each Phase 3 trial was the subject of a SPA with the FDA. The primary endpoint of both studies is to evaluate the relative diagnostic efficacy of the NAV5001 SPECT images compared with the diagnosis made by neurologists and that established by a consensus panel of three movement disorder specialists as the 'Standard of Truth.' In one study, each subject will undergo SPECT imaging with NAV5001 only. In the second study, subjects will undergo SPECT imaging with both NAV5001 and an alternative SPECT agent, ioflupane, in a cross-over comparison design.

In November 2013, the patent protection supporting NAV5001 was expanded through the issuance of a new United States patent to which Navidea has rights through its license for NAV5001.

RIGScan

RadioImmunoGuided Surgery (RIGS®) is a technique to provide diagnostic information regarding tumor or metastatic disease during or in association with cancer surgery. RIGS is intended to enable a surgeon to identify cancerous tissue and delineate tumor or occult or metastatic cancerous tissue "targeted" through the use of RIGScan, a radiolabeled, cancer-specific targeting monoclonal antibody. RIGScan is administered to the patient and is identified by imaging or, during surgery, with a gamma detection probe, thereby assisting a surgeon in identifying the location of cancerous tissues. Our RIGScan technology is a radiolabeled monoclonal antibody that serves as the biologic targeting agent for intraoperative detection of occult or metastatic cancer. The antibody localizes or binds to a tumor antigen called TAG-72 expressed on many solid tumor cancers. RIGScan is intended to aid in identifying a primary tumor, ascertaining margins, or determining the extent and location of occult and metastatic tumor in patients with solid tumor cancers that express the TAG-72 antigen, 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 of disease, and therefore may impact the surgical and therapeutic management of the patient.

The murine monoclonal antibody of RIGScan has been studied in several clinical trials, including Phase 3 studies. Results from certain of these studies have been published in leading cancer journals including Clinical Cancer Research, Annals of Surgical Oncology and Diseases of the Colon and Rectum. In 1996, Navidea submitted applications to the EMA and the FDA for marketing approval of RIGScan for the detection of metastatic colorectal cancer based primarily on results of a single Phase 3 clinical trial, NEO2-14. The FDA declined approval, indicating that, in addition to identifying additional pathology-confirmed disease, the clinical studies of RIGScan needed to demonstrate clinical utility in enhancing patient outcomes, an endpoint which the completed studies were not designed to address. Navidea withdrew its application to the EMA in November 1997.

To support resuming RIGScan development, we filed a new investigational new drug (IND) request with the FDA in late 2010. In a pre-IND meeting with the FDA in February 2011, the FDA provided guidance regarding our manufacturing process, to increase manufacturing efficiency and the quality of the underlying biologic antibody and potentially transitioning from a murine-based monoclonal antibody to a human-based monoclonal antibody. In August 2011, we also held a meeting with the SAWP of the EMA and received similar guidance. With this collective guidance, we transitioned from a murine monoclonal antibody used in the previous studies noted above to a humanized monoclonal antibody.

In September 2012, we were awarded a grant from the NIH to further develop RIGScan. The first phase of the grant, which has been awarded, is for $315,000; the second phase of the grant, which requires that we meet certain conditions, primarily completion of the first phase, development of a protocol, and institutional review board approval, will be for an additional $1.2 million. We have focused on manufacturing the humanized antibody with the aim of completing the necessary manufacturing steps to support clinical development, have developed an initial protocol to study the antibody in clinical trials, and have identified clinical collaborators. However, as the scope and required resources for the RIGScan program continues to be assessed, particularly in light of other development opportunities such as Lymphoseek, NAV4694, NAV5001, our Manocept platform, or other agents, the timing and scope of our plans for RIGScan may be further affected.

RIGScan is a biologic drug that has not been produced for several years. We will need to establish robust manufacturing and radiolabeling capabilities for the antibody in order to meet the regulatory needs for the RIGScan product. We cannot assure you, however, that further clinical trials for this product will be successful, that it will achieve regulatory approval, or if approved, that it will achieve market acceptance.

Outlook

In connection with the U.S. approval of Lymphoseek in March 2013, the Company has now undertaken the initial stages of commercial launch in the U.S. with our marketing partner, Cardinal Health, with an official announcement of launch in May 2013. As such, we began reporting revenue from Lymphoseek beginning in the second quarter of 2013. Our sales margins since launch have been negatively impacted by the proportion of sales of lower-margin inventory stocking units and testing activities required by the FDA. Our longer-term expectations for gross margins will increase as these charges diminish as a proportion of revenue, and continue to be in line with previous estimates. As insight into the sales process with Lymphoseek grows, we expect to provide increasing guidance over the next several quarters such that by the second quarter of 2014, revenue guidance and margins become primary metrics with which to assess performance. However, the Company currently believes Lymphoseek has the potential to achieve a market leadership position among lymphatic mapping agents in the U.S. over the next twelve to eighteen months.

Our operating expenses in recent years have been focused primarily on support of Lymphoseek, NAV4694 and NAV5001 product development, and to a lesser extent, on efforts to restart active development of RIGScan. In addition, we began initial evaluation of our Manocept platform in 2013. We spent approximately $14.3 million and $12.5 million on research and development activities during the nine-month periods ended September 30, 2013 and 2012, respectively. Of the total amounts we spent on research and development during those periods, excluding costs related to our internal research and development headcount and our general and administrative staff which we do not currently allocate among the various development programs that we have underway, we incurred charges by program as follows:

	Nine Months Ended September 30,			
Development Program	2013		2012	
Lymphoseek	$1,941,110	(a)	$4,243,933	
Manocept Platform	320,774		—	
NAV4694	5,325,207		2,177,007	
NAV5001	739,677		2,083,699	(b)
RIGScan	66,031		254,721	

(a) Amount includes pre-approval development and post-commercialization label expansion costs.
(b) Amount includes approximately $1.8 million in option and sublicense fees paid in 2012.

Due to the advancement of our efforts with Lymphoseek, our Manocept platform, NAV4694, NAV5001, and RIGScan, we expect our total drug-related development and commercialization expenses for the remainder of 2013 to continue to be higher than in 2012. The specific levels to which each program's expenditures may rise will depend in part on how successful we are in commercializing Lymphoseek and on the extent to which we draw on the other financial resources we have at our disposal. In general, development expenses in 2013 for Lymphoseek and RIGScan are expected to decrease as compared to 2012 while expenses related to our Manocept platform, NAV4694, and NAV5001 are all currently expected to increase in 2013 over 2012.

Lymphoseek was approved and indicated for use in lymphatic mapping for breast cancer and melanoma by the FDA in March 2013. During the remainder of 2013, we expect to continue to incur significant general marketing support as well as medical education expenses related to Lymphoseek. Although our marketing partner will bear the direct marketing, sales and distribution costs related to the sale of Lymphoseek, we expect that our costs to support product launch and medical education-related activities associated with Lymphoseek could approach approximately $5-6 million in out-of-pocket charges in 2013, compared to approximately $3 million in 2012. We expect to incur additional development expenses related to supporting the MAA review of Lymphoseek in the EU and studies to

support the sNDA submission for Lymphoseek to the FDA in a potential post-commercialization setting, and support the other product activities related to the potential marketing registration of Lymphoseek in other markets. We cannot assure you that Lymphoseek will achieve regulatory approval in the EU or any other market outside the U.S., or if approved, that it will achieve market acceptance in the U.S. or any other market.

We are currently evaluating existing and emerging data on the use of Manocept-related agents in the diagnosis and disease-staging of macrophage-mediated disorders such as KS, TB, RA 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 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. 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.

We expect to incur significant expenses for NAV4694 during the remainder of 2013 related to ongoing Phase 2 clinical trials and a pivotal Phase 3 clinical trial in subjects with AD, as well as costs for manufacturing-related activities required prior to filing for regulatory clearance to market. We also expect to incur significant expenses for NAV5001 during the remainder of 2013 related to support of Phase 2 and Phase 3 clinical trials, as well as for manufacturing-related activities required to support our clinical trial and registration efforts. Currently, neither NAV4694 nor NAV5001 is expected to contribute revenue to the Company until at least 2016 or 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.

We are in the process of evaluating the business, manufacturing, development and regulatory pathways forward with respect to RIGScan. In the near-term, our development efforts related to RIGScan will likely be limited to those which we are able to fund through external sources such as the Small Business Innovation Research grant from the National Institutes of Health we were awarded in 2012. We believe that the time required for continued development, regulatory approval and commercialization of a RIGScan product would likely be a minimum of five years before we receive any significant product-related royalties or revenues. We cannot assure you that we will be able to complete satisfactory development arrangements or obtain incremental financing to fund development of the RIGS technology 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, 2013 and 2012

Net Sales and Margins. Net sales of Lymphoseek were $144,000 during the third quarter of 2013. We did not record any sales revenue during the third quarter of 2012. Gross margins on net sales were 48% for the third quarter of 2013. Cost of goods sold included a royalty on net sales payable under our license agreement with the University of California, San Diego (UCSD) and post-production testing activities required by regulatory authorities, which are charged as one-time period costs.

Grant and Other Revenue. During the third quarter of 2013, we recognized $257,000 of grant revenue. SBIR grants from the NIH supporting RIGScan and NAV4694 development accounted for $181,000 of the revenue recognized. The remaining grant revenue was received from Ohio Third Frontier related to the development of alternative uses of Lymphoseek and support of student internships. We did not recognize any grant revenue during the third quarter of 2012.

Research and Development Expenses. Research and development expenses increased $151,000, or 2%, to $6.3 million during the third quarter of 2013 from $6.1 million during the same period in 2012. The increase was primarily due to net increases in drug project expenses related to (i) increased NAV4694 development costs of $1.1 million including increased clinical trial costs coupled with increased manufacturing-related activities, and (ii) increased Manocept platform development costs of $321,000; offset by (iii) decreased NAV5001 development costs of $1.1 million including licensing fees of $1.3 million in 2012 offset by increased manufacturing-related activities, and (iv) net decreased Lymphoseek development costs of $794,000, primarily decreased manufacturing-related and regulatory consulting costs. The net increase in research and development expenses also included increased compensation including incentive-based awards and other related expenses of $692,000 related to increased headcount required for expanded development efforts, as well as increased travel and other support costs.

Selling, General and Administrative Expenses. Selling, general and administrative expenses increased $1.1 million, or 35%, to $4.0 million during the third quarter of 2013 from $2.9 million during the same period in 2012. The net increase was primarily due to increased medical education costs to support Lymphoseek of $749,000, increased compensation including incentive-based awards and other related expenses of $341,000 related to increased headcount, and increased legal and professional services costs, offset by decreased out-of-pocket marketing costs related to the commercial launch of Lymphoseek of $473,000.

Other Income (Expense). Other expense, net, was $1.4 million during the third quarter of 2013 as compared to $29,000 during the same period in 2012. Interest expense increased $661,000 to $976,000 during the third quarter of 2013 from $315,000 for the same period in 2012, primarily due to the interest related to the GECC/MidCap loan in 2013, offset by interest related to the Hercules loan in 2012. Of this interest expense, $258,000 and $147,000 in the third quarter of 2013 and 2012, respectively, was non-cash in nature related to the amortization of debt issuance costs and non-cash debt discounts related to the GECC/MidCap and Hercules notes. During the third quarter of 2013 and 2012, we recorded expense of $377,000 and income of $284,000, respectively, related to changes in the estimated fair value of financial instruments.

Nine Months Ended September 30, 2013 and 2012

Net Sales and Margins. Net sales of Lymphoseek were $272,000 during the first nine months of 2013. We did not record any sales revenue during the same period in 2012. Gross margins on net sales were 33% for the first nine months of 2013. Cost of goods sold included a royalty on net sales payable under our license agreement with UCSD. During the nine months ended September 30, 2013, margins on Lymphoseek sales were negatively impacted due to the proportion of sales made up of lower margin inventory-stocking units, coupled with post-production testing activities required by regulatory authorities, which are charged as one-time period costs, including certain post-manufacture testing costs related to normal ongoing processes required by the FDA.

Grant and Other Revenue. During the first nine months of 2013, we recognized $248,000 of grant revenue related to SBIR grants from the NIH to support RIGScan and NAV4694 development. Grant revenue of $75,000 was received from Ohio Third Frontier and provided $50,000 toward the development of alternative uses of Lymphoseek and $25,000 supporting student internships. During the first nine months of 2012, we recognized $60,000 of revenue related to reimbursement of certain Lymphoseek commercialization activities by our distribution partner, Cardinal Health, and $12,000 related to Ohio Third Frontier grants supporting student internships.

Research and Development Expenses. Research and development expenses increased $1.8 million, or 14%, to $14.3 million during the first nine months of 2013 from $12.5 million during the same period in 2012. The increase was primarily due to net increases in drug project expenses related to (i) increased NAV4694 development costs of $3.1 million including increased clinical trial costs coupled with increased manufacturing-related activities, and (ii) increased Manocept platform development costs of $321,000; offset by (iii) a net decrease in Lymphoseek development costs of $2.3 million resulting from decreased manufacturing-related costs, decreased regulatory consulting costs related to preparation for a potential FDA Advisory Committee meeting in 2012, and decreased clinical trial costs, and (iv) a net decrease in NAV5001 development costs of $1.3 million including licensing fees of $1.8 million in 2012 coupled with decreased consulting costs, offset by increased manufacturing-related costs and clinical trial activities. The net increase in research and development expenses also included increased compensation including incentive-based awards and other related expenses of $2.2 million related to increased headcount required for expanded development efforts, as well as increased travel and other support costs.

Selling, General and Administrative Expenses. Selling, general and administrative expenses increased $3.0 million, or 36%, to $11.5 million during the first nine months of 2013 from $8.5 million during the same period in 2012. The net increase was primarily due to increased medical education costs to support Lymphoseek of $1.9 million and increased

compensation including incentive-based awards and other expenses of $1.0 million related to increased headcount, offset by decreased out-of-pocket marketing costs related to the commercial launch of Lymphoseek of $1.0 million.

Other Income (Expense). Other expense, net, was $3.6 million during the first nine months of 2013 as compared to $960,000 during the same period in 2012. Interest expense increased $874,000 to $1.8 million during the first nine months of 2013 from $930,000 for the same period in 2012, primarily due to the interest related to the GECC/MidCap loan as well as the draws on the Montaur credit facility, offset by the decreased balance of the Hercules note payable. Of this interest expense, $502,000 and $407,000 in the first nine months of 2013 and 2012, respectively, was non-cash in nature related to the amortization of debt issuance costs and debt discounts related to the GECC/MidCap and Hercules notes. During the first nine months of 2013, we recorded losses on extinguishment of debt of $943,000 related to the modification of the Montaur note and $429,000 upon paying off the balance of the Hercules note. For the nine months ended September 30, 2013 and 2012, we recorded non-cash expense of $377,000 and income of $7,000, respectively, related to changes in the estimated fair value of financial instruments.

Liquidity and Capital Resources

Cash balances increased to $44.6 million at September 30, 2013 from $9.1 million at December 31, 2012. The net increase was primarily due to net proceeds from the issuance of common stock of $39.6 million, net proceeds from the GECC/MidCap note payable of $23.8 million, and draws on our Montaur credit facility of $4.0 million, offset by cash used to fund our operations, mainly for research and development activities, of $24.5 million, principal payments on our notes payable of $6.0 million, purchases of equipment of $763,000, and payment of employee minimum tax withholdings related to stock-based compensation of $659,000. The current ratio increased to 7.6:1 at September 30, 2013 from 1.7:1 at December 31, 2012.

Operating Activities. Cash used in operations increased $7.9 million to $24.5 million during the first nine months of 2013 compared to $16.6 million during the same period in 2012.

Accounts receivable increased to $158,000 at September 30, 2013 from $18,000 at December 31, 2012, primarily due to receivables due from Cardinal Health for sales of Lymphoseek and from the NIH for SBIR grants.

Inventory levels increased to $2.0 million at September 30, 2013 from $298,000 at December 31, 2012. Increases in work-in-process and finished goods were related to in-process and completed new lots of Lymphoseek finished drug. Increases in materials were related to purchases of Lymphoseek drug substance. We expect inventory levels to increase over the remainder of 2013 as we produce additional Lymphoseek inventory to support commercial sales following our recent product launch.

Accounts payable increased to $1.7 million at September 30, 2013 from $1.4 million at December 31, 2012, primarily due to normal fluctuations in timing of receipt and payment of invoices. Accrued liabilities and other current liabilities increased to $2.9 million at September 30, 2013 from $2.0 million at December 31, 2012, primarily due to the increases in accrued NAV4694 and Manocept platform development costs and net increases in compensation-related accruals. Our payable and accrual balances will continue to fluctuate but will likely increase overall as we increase our level of commercial activity related to Lymphoseek, and development activity related to the Manocept platform, NAV4694, NAV5001, RIGScan, and other potential product candidates.

Investing Activities. Investing activities used $791,000 during the first nine months of 2013 compared to using $624,000 during the same period in 2012. 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. Capital expenditures of $618,000 during the first nine months of 2012 were primarily for equipment to be used in the production of NAV4694 and Lymphoseek, software, computers, and furniture and fixtures. We expect our overall capital expenditures for 2013 in total will be higher than in 2012.

Financing Activities. Financing activities provided $60.8 million during the first nine months of 2013 compared to $204,000 used during the same period in 2012. 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. The $204,000 used in financing activities in the first nine months of 2012 consisted primarily of principal payments on our notes payable of $620,000 and payments of debt issuance costs of $154,000, offset by proceeds from the issuance of common stock of $759,000.

GECC/MidCap Debt

In June 2013, we executed a Loan and Security Agreement (the Loan Agreement) with General Electric Capital Corporation (GECC) and MidCap Financial SBIC, LP (MidCap), providing for a loan to the Company of $25 million. Pursuant to the Loan Agreement, we issued GECC and MidCap: (1) Term Notes in the aggregate principal amount of $25,000,000, bearing interest at 9.83%, and (2) Series HH Warrants to purchase an aggregate of 301,205 shares of our common stock at an exercise price of $2.49 per share, expiring in June 2023 (the Series HH Warrants). The Loan Agreement provides for an interest-only period beginning on June 25, 2013 and expiring on June 30, 2014. The principal and interest is to be repaid in 30 equal monthly installments, payable on the first of each month following the expiration of the interest-only period, and one final payment in an amount equal to the entire remaining principal balance of the Term Note on the maturity date. The outstanding balance of the debt is due December 23, 2016. On the date upon which the outstanding principal amount of the loan is paid in full, the Company will be required to pay a non-refundable end-of-term fee equal to 4.0% of the original principal amount of the loan. The Loan Agreement also specifies certain covenants including the requirement that Navidea maintains a minimum cash balance greater than six times its monthly cash burn amount. During the first nine months of 2013, we recorded interest expense of $943,000 on our notes payable to GECC and MidCap, which includes amortization of the debt discount and issuance costs. As of September 30, 2013, the remaining outstanding principal balance of the debt was $25.0 million, and the Series HH Warrants remain outstanding.

Hercules Debt

In December 2011, we executed a Loan and Security Agreement (the Loan Agreement) with Hercules Technology II, L.P. (Hercules). Pursuant to the Loan Agreement, we issued Hercules: (1) a Secured Term Promissory Note in the principal amount of $7,000,000, bearing interest at the greater of either (a) the U.S. Prime Rate as reported in The Wall Street Journal plus 6.75%, or (b) 10.0%, and (2) a Series GG warrant to purchase 333,333 shares of our common stock at an exercise price of $2.10 per share, expiring in December 2016 (the Series GG Warrant). During the period from January 1, 2013 through June 24, 2013, we paid $1.3 million of principal payments and recorded interest expense of $472,000 on our note payable to Hercules, which includes amortization of the debt discount and issuance costs. On June 25, 2013, the Company used a portion of the proceeds from the GECC/MidCap loan to pay the remaining $4.4 million of principal outstanding on the Hercules note, as well as a $250,000 end-of-term fee and a $66,000 early payment penalty in accordance with the terms of the Hercules note. As of September 30, 2013, the note payable to Hercules was no longer outstanding. The Series GG Warrant remains outstanding.

Montaur Credit Facility

In July 2012, we entered into an agreement with Platinum-Montaur Life Sciences, LLC (Montaur) to provide us with a credit facility of up to $50 million. Following the approval of Lymphoseek, Montaur was committed under the terms of the agreement to extend up to $35 million in debt financing to the Company at an interest rate equal to the greater of (a) the U.S. Prime Rate as reported in the Wall Street Journal plus 6.75%; (b) 10.0%; or (c) the highest rate of interest then payable pursuant to the Hercules Loan Agreement plus 0.125%. Through June 25, 2013, we drew a total of $8.0 million under the original facility. The agreement also provides for Montaur to extend an additional $15 million on terms to be negotiated. Principal amounts are due the earlier of two years from the date of draw or June 30, 2016.

In connection with entering into the GECC/MidCap Loan Agreement, the Company and Montaur entered into an Amendment to the July 2012 Loan Agreement (the Montaur Amendment). Navidea, Montaur, and GECC/MidCap also entered into a Subordination Agreement, providing for subordination of the Company’s indebtedness under the Montaur credit facility to the Company’s indebtedness under the GECC/MidCap Loan Agreement, among other customary terms and conditions.

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Concurrent with the execution of the Montaur Amendment, the Company delivered an Amended and Restated Promissory Note (the Amended Montaur Note) to Montaur, which amends and restates the original promissory note issued to Montaur, in the principal amount of up to $35,000,000. The Amended Montaur Note also adjusts the interest rate to the greater of (a) the U.S. Prime Rate as reported in the Wall Street Journal plus 6.75%; (b) 10.0%; or (c) the highest rate of interest then payable pursuant to the GECC/MidCap Loan Agreement plus 0.125% (effective interest rate at September 30, 2013 was 10%). In addition, the Montaur Amendment grants Montaur the right, at Montaur's option subject to certain conditions, to convert all or any portion of the unpaid principal or unpaid interest accrued on any future draw (the Conversion Amount), beginning on a date two years from the date the draw was advanced, into the number of shares of Navidea's common stock computed by dividing the Conversion Amount by a conversion price equal to the lesser of (i) 90% of the lowest VWAP for the 10 trading days preceding the date of such conversion request, or (ii) the average VWAP for the 10 trading days preceding the date of such conversion request. The Montaur Amendment also provides a conversion right on the same terms with respect to the amount of any mandatory repayment due following the Company achieving $2,000,000 in cumulative revenues from sales or licensing of Lymphoseek. The conversion option applies to the Conversion Amount if the Company is prohibited from making such prepayment under the terms of the Subordination Agreement.

Also in connection with the Montaur Amendment, the Company and Montaur entered into a Warrant Exercise Agreement (Exercise Agreement), pursuant to which Montaur exercised its Series X Warrant and Series AA Warrant. The warrants were exercised on a cashless basis by canceling a portion of the indebtedness outstanding under the Montaur Loan Agreement equal to $4,781,333, the aggregate exercise price of the warrants. Pursuant to the Exercise Agreement, in lieu of common stock, Montaur received on exercise of the warrants 2,364.9 shares of the Company's Series B, convertible into 7,733,223 shares of our common stock in the aggregate (3,270 shares of common stock per preferred share).

During the first nine months of 2013, we drew a total of $4.0 million under the Montaur credit facility and recorded interest expense of $386,000. As of September 30, 2013, the remaining outstanding principal balance was $3.2 million, with $31.8 million still available under the credit facility.

In July 2013, Montaur converted 580 shares of the Series B into 1,896,600 shares of our common stock under the terms of the Series B. In September 2013, Montaur converted 710.9 shares of the Series B into 2,324,643 shares of our common stock, also under the terms of the Series B. As of September 30, 2013, there are 8,012 shares of Series B outstanding which are convertible into 26,199,240 shares of our common stock.

2013 Public Offerings

We filed a shelf registration statement in 2011 to provide us with future funding alternatives and flexibility as we execute on our plans to achieve our product development and commercialization goals, as well as evaluating and acting on opportunities to expand our product pipeline. In February 2013, we completed a public offering of 1,542,389 shares of the Company's common stock at a price of $3.10 per share (the February 2013 Offering). The net proceeds to the Company were approximately $4.5 million after deducting expenses associated with the February 2013 Offering. In April 2013, we completed another public offering of 2,100,000 shares of the Company's common stock at a price of $2.43 per share (the April 2013 Offering). The net proceeds to the Company were approximately $4.8 million after deducting expenses associated with the April 2013 Offering. The February 2013 and April 2013 Offerings were underwritten by Ladenburg Thalmann & Co. Inc. and were made pursuant to the Company's existing effective shelf registration statement on Form S-3.

In September 2013, we entered into a Securities Purchase Agreement with Crede for a registered direct public offering of 10,563,381 shares of our common stock at a price of $2.84 per share for total gross proceeds of $30.0 million. In addition to the common stock, we issued Series JJ warrants to purchase 3,169,015 shares of our common stock at an

exercise price of $3.83 per share, expiring on September 24, 2016.

Crede can exercise the Series JJ warrants at any time at a strike price of $3.83. The warrant agreement also provides for the potential exchange of warrants into Navidea common stock for no additional consideration starting six months after the date of the Securities Purchase Agreement if, at the time of the exchange, the closing bid price for Navidea's common stock is below $3.83. The amount of shares issuable on a potential exchange is based on dividing a Black-Scholes valuation of the warrants by the closing bid price for Navidea's common stock on the date of the exchange. However, as a number of the key inputs to the Black-Scholes calculation are fixed under the terms of the warrant agreement, the Company does not expect the Black-Scholes valuation on the date of a potential exchange to vary materially from the derivative liability of $7.7 million which was reported related to the Series JJ warrants as of September 30, 2013. Based on this valuation, the Company has estimated the number of shares issuable on a potential exchange to be between 2.1 million shares (based on a potential exchange price of $3.83) and 3.8 million shares (based on the floor exchange price of $2.00).

The net proceeds to the Company were approximately $28.8 million after deducting expenses associated with the Securities Purchase Agreement, including placement agent fees of $999,000 (3.3% of the gross proceeds). The common stock, warrants, and shares of common stock underlying the warrants were issued pursuant to the Company's existing effective shelf registration statement on Form S-3.

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.

We believe that our current cash balance, our credit facility with Montaur, our projected revenue derived from U.S. sales of Lymphoseek following the recent commercial launch, 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 intent to raise funds through approaching the equity capital markets, provide us with adequate financial resources to continue to fund our business plan. 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 Pronouncements

In February 2013, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2013-02, Comprehensive Income (Topic 220). ASU 2013-02 provides entities with two basic options for reporting the effect of significant reclassifications – either (1) on the face of the statement where net income is presented or (2) as a separate footnote disclosure. Public entities will report reclassifications in both annual and interim periods. Under option 1, the effect of significant reclassifications is presented parenthetically by component of other comprehensive income (OCI) on the respective line items of net income. Entities must also parenthetically report the aggregate tax effect of reclassifications in the income tax expense (benefit) line item. Under option 2, the significant amounts of each component of OCI must be presented in a single footnote. ASU 2013-02 is effective prospectively for reporting periods beginning after December 15, 2012. ASU 2013-02 did not have an effect on our consolidated financial

statements.

In July 2013, the FASB issued ASU No. 2013-11, Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists (ASU 2013-11). ASU 2013-11 requires an entity to present an unrecognized tax benefit in the financial statements as a reduction to a deferred tax asset for a net operating loss (NOL) carryforward, a similar tax loss, or a tax credit carryforward except when: (1) a NOL carryforward, a similar tax loss, or a tax credit carryforward is not available as of the reporting date under the governing tax law to settle taxes that would result from the disallowance of the tax position; or (2) the entity does not intend to use the deferred tax asset for this purpose (provided that the tax law permits a choice). If either of these conditions exists, an entity should present an unrecognized tax benefit in the financial statements as a liability and should not net the unrecognized tax benefit with a deferred tax asset. ASU 2013-11 does not affect the recognition or measurement of uncertain tax positions under ASC 740. ASU 2013-11 is effective for fiscal years, and interim periods within those years, beginning after December 15, 2013. ASU 2013-11 should be applied prospectively to all unrecognized tax benefits that exist at the effective date. Retrospective application is permitted. We do not expect ASU 2013-11 to have an impact on our consolidated financial statements.

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 generate additional revenue from grants to support various product development initiatives. We generally recognize grant revenue when expenses reimbursable under the grants have been incurred and payments under the grants become contractually due. We also recognize revenue from the reimbursement by our partners of certain expenditures for which the Company has principal responsibility.

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, CMC-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, 2013, our $44.6 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, 2013, 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, 2013, 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-month periods ended September 30, 2013 and 2012, we recorded foreign currency transaction losses of approximately $22,000 and $13,000, 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 warrant liabilities is determined using various inputs and assumptions, one of which is the price of Company stock. As of September 30, 2013, we had approximately $7.7 million of derivative liabilities recorded on our balance sheet related to 3,169,015 Series JJ warrants. A hypothetical 50% increase in our stock price would increase the value of our derivative liabilities by approximately $4.2 million. A hypothetical 50% decrease in our stock price would decrease the value of our derivative liabilities by approximately $2.7 million.

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, 2013. 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, 2013, there were no changes in our internal control over financial reporting that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1A. Risk Factors

The following changes have been made to the Company's risk factors as previously disclosed in the Company's Annual Report on Form 10-K for the year ended December 31, 2012, filed with the SEC on March 18, 2013.

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

All of our material assets, except our intellectual property, have been pledged as collateral for our borrowings under the Loan and Security Agreement (the Loan Agreement) with General Electric Capital Corporation (GECC) and MidCap Financial SBIC, LP (MidCap).

In addition to the security interest in our assets, the Loan Agreement carries substantial covenants that impose significant requirements on us, including, among others, requirements that:

- we pay all principal, interest and other charges on the outstanding balance of the borrowed funds when due;
- we keep reserved out of our authorized shares of common stock sufficient shares to satisfy our obligation to issue shares upon the exercise of the warrants issued in connection with the Loan and Security Agreement;
- we provide certain financial information and reports to GECC and MidCap in a timely manner;
- we maintain a minimum balance of cash and cash equivalents as defined in the Loan Agreement; and
- we indemnify GECC and MidCap against certain liabilities.

The requirement that we maintain a minimum cash balance may limit our ability to fully utilize the proceeds of the GECC/MidCap loan to fund our operations.

Additionally, with certain exceptions, the Loan Agreement prohibits us from:

- amending our organizational or governing agreements and documents;
- entering into any merger or consolidation;
- dissolving the Company or liquidating its assets, or acquiring all or any substantial part of the business or assets of any other person;
- incurring any indebtedness, other than permitted indebtedness;
- granting or permitting liens against our assets, other than permitted liens;
- acquiring or making investments in any other person other than permitted investments;
- making any material dispositions of our assets, except for permitted dispositions; or
- declaring or paying any dividends or making any other distributions.

Our ability to comply with these provisions may be affected by changes in our business condition or results of our operations, or other events beyond our control. The breach of any of these covenants would result in a default under the Loan Agreement, permitting GECC and MidCap to accelerate the maturity of the debt and to sell the assets securing it. Such actions by GECC and MidCap could materially adversely affect our operations, results of operations and financial condition, including causing us to substantially curtail our product development activities.

In addition, our Loan Agreement with Platinum-Montaur Life Sciences, LLC (Montaur) carries covenants typical for commercial loan agreements, and similar to those contained in the GECC/MidCap Loan Agreement, that impose significant requirements on us. Our ability to comply with these provisions may be affected by changes in our business condition or results of our operations, or other events beyond our control. The breach of any of these

covenants would result in a default under the Loan Agreement, permitting Montaur to terminate our ability to obtain additional draws under the Loan Agreement and accelerate the maturity of the debt. Such actions by Montaur could materially adversely affect our operations, results of operations and financial condition, including causing us to substantially curtail our product development activities.

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

Montaur may exercise the right to convert all or any portion of the unpaid principal or unpaid interest accrued on any future draw into shares of Navidea's common stock. Montaur may also exercise a conversion right on the amount of any mandatory repayment due following the Company achieving $2,000,000 in cumulative revenues from sales or licensing of Lymphoseek. The conversion option applies to the Conversion Amount if the Company is prohibited from making such repayment under the terms of the Subordination Agreement. If Montaur exercises any or all of its conversion rights, the percentage ownership of our current stockholders will be reduced. The issuance of additional common stock may also result in dilution in the net tangible book value per share of our common stock.

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

(a) On July 29, 2013 we issued 1,896,600 shares of our common stock to Montaur in exchange for 580 shares of our Series B Convertible Preferred Stock in connection with Montaur's exercise of its conversion option pursuant to the terms of our Series B Convertible Preferred Stock. On September 18, 2013, we issued 850,200 shares of our common stock in exchange for 260 shares of our Series B Convertible Preferred Stock, and on September 25, 2013, we issued 1,474,443 shares of our common stock in exchange for 450.9 shares of our Series B Convertible Preferred Stock, in connection with Montaur's exercise of conversion options pursuant to the terms of our Series B Convertible Preferred Stock. The conversion terms for each of these issuances was 3,270 shares of our common stock in exchange for each share of our Series B Convertible Preferred Stock. The issuances of these securities were exempt from registration under Section 3(a)(9) of the Securities Act.

(b) There were no repurchases of our common stock during the three-month period ended September 30, 2013.

Item 5. Other Information.

On November 7, 2013, the Company's Board of Directors adopted an amendment to the Company's Amended and Restated By-Laws. This amendment added new Section 7 to Article VII of the Amended and Restated Bylaws, to designate the Court of Chancery of the State of Delaware as the appropriate forum for certain actions brought on behalf of the Company, arising pursuant to the Delaware General Corporation Law, or governed by the internal affairs doctrine. Previously, the Amended and Restated By-Laws were silent with respect to the appropriate forum for such actions. The amendment was effective immediately upon the date of its adoption by the Company's Board of Directors.

The summary of the amendment set forth above is qualified in its entirety by the full text of the Amended and Restated Bylaws filed herewith as Exhibit 3.2, which is incorporated herein by this reference.

Item 6. Exhibits

3.2	Amended and Restated By-Laws of Navidea Biopharmaceuticals, Inc. (as adopted November 7, 2013)*
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*
32.1	Certification of Chief Executive Officer of Periodic Financial Reports pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350.*
32.2	Certification of Chief Financial Officer of Periodic Financial Reports pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350.*
101.INS	XBRL Instance Document**
101.SCH	XBRL Taxonomy Extension Schema Document**
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document**
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document**
101.LAB	XBRL Taxonomy Extension Label Linkbase Document**
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document**

* Filed herewith.

** Furnished herewith.

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

SIGNATURES

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

NAVIDEA BIOPHARMACEUTICALS, INC.
(the Company)
November 12, 2013

By: /s/ Mark J. Pykett

Mark J. Pykett, V.M.D., Ph.D.
Chief Executive Officer
(duly authorized officer; principal executive officer)

By: /s/ Brent L. Larson

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

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