

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended 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 No

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

Yes No

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

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

Yes No

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date: 134,345,483 shares of common stock, par value \$.001 per share (as of the close of business on November 5, 2013).

NAVIDEA BIOPHARMACEUTICALS, INC. and SUBSIDIARIES

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PART I – FINANCIAL INFORMATION

Item 1. Financial Statements

Navidea Biopharmaceuticals, Inc. and Subsidiaries Consolidated Balance Sheets

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
	<u>47,623,370</u>	<u>10,617,383</u>
Property and equipment	2,779,659	2,026,895
Less accumulated depreciation and amortization	1,400,559	1,092,317
	<u>1,379,100</u>	<u>934,578</u>
Patents and trademarks	143,370	115,053
Less accumulated amortization	25,523	22,571
	<u>117,847</u>	<u>92,482</u>
Deferred debt issuance costs and other	816,391	327,954
	<u>816,391</u>	<u>327,954</u>
Total assets	<u>\$ 49,936,708</u>	<u>\$ 11,972,397</u>

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	<u>400,374</u>	<u>—</u>	<u>595,651</u>	<u>71,931</u>
Cost of goods sold	75,422	—	180,860	—
Gross profit	<u>324,952</u>	<u>—</u>	<u>414,791</u>	<u>71,931</u>
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	<u>10,249,631</u>	<u>9,069,397</u>	<u>25,800,148</u>	<u>21,034,691</u>
Loss from operations	<u>(9,924,679)</u>	<u>(9,069,397)</u>	<u>(25,385,357)</u>	<u>(20,962,760)</u>
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	<u>(1,381,528)</u>	<u>(29,203)</u>	<u>(3,562,220)</u>	<u>(959,734)</u>
Net loss	<u>(11,306,207)</u>	<u>(9,098,600)</u>	<u>(28,947,577)</u>	<u>(21,922,494)</u>
Preferred stock dividends	<u>—</u>	<u>(25,000)</u>	<u>—</u>	<u>(75,000)</u>
Net loss attributable to common stockholders	<u>\$ (11,306,207)</u>	<u>\$ (9,123,600)</u>	<u>\$ (28,947,577)</u>	<u>\$ (21,997,494)</u>
Loss per common share (basic and diluted)	<u>\$ (0.09)</u>	<u>\$ (0.09)</u>	<u>\$ (0.25)</u>	<u>\$ (0.23)</u>
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 Capital	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount			
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	<u>(24,456,611)</u>	<u>(16,604,696)</u>
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	<u>(791,186)</u>	<u>(623,668)</u>
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	<u>60,761,837</u>	<u>(204,470)</u>
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	<u>\$ 44,632,604</u>	<u>\$ 11,211,170</u>

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	<u>4,923,352</u>	<u>\$ 2.36</u>	<u>7.3 years</u>	<u>\$ 2,976,564</u>
Exercisable at end of period	<u>2,128,540</u>	<u>\$ 1.49</u>	<u>5.1 years</u>	<u>\$ 2,796,288</u>

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	<u>622,000</u>	<u>\$ 2.75</u>

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

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 repayment 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.

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.

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 NEO3-06. The results, published independently by this single clinical trial site in our larger Phase 3 NEO3-06 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 Erythematosus, 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 β -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:

Development Program	Nine Months Ended September 30,	
	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 Manoccept 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 Manoccept 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.

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)

INDEX TO EXHIBITS

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* Filed herewith.

** Furnished herewith.

NAVIDEA BIOPHARMACEUTICALS, INC.

AMENDED AND RESTATED BY-LAWS

AS AMENDED JULY 18, 1995, MAY 30, 1996, JULY 26, 2007, AND NOVEMBER 7, 2013

ARTICLE I

OFFICES

SECTION 1. REGISTERED OFFICE. The registered office of the corporation in the state of Delaware shall be located at Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware, County of New Castle. The name of the corporation's registered agent at such address shall be the Corporation Trust Company. The registered office and/or registered agent of the corporation may be changed from time to time by action of the board of directors.

SECTION 2. OTHER OFFICES. The corporation may also have offices at such other places, both within and without the state of Delaware, as the board of directors may from time to time determine or the business of the corporation may require.

ARTICLE II

MEETINGS OF STOCKHOLDERS

(The following section was amended by the Board of Directors on July 26, 2007)

SECTION 1. ANNUAL MEETINGS. An annual meeting of the stockholders for the election of directors shall be held at such time and place either within or without the State of Delaware as shall be designated on an annual basis by the board of directors and stated in the notice of the meeting. Any other proper business may be transacted at the annual meeting. The board of directors may, in its sole discretion, determine that any annual meeting of stockholders and/or any special meeting of stockholders shall not be held at any place, but may instead be held wholly by means of remote communication, as permitted by Delaware law. In addition, the Board of Directors may, in its sole discretion, determine that any annual meeting of stockholders and/or any special meeting of stockholders may be held partially by remote communication, as permitted by Delaware law. The Board of Directors may adopt guidelines and procedures for meetings conducted wholly or partially by remote communication.

(The following section was amended by the Board of Directors on July 18, 1995)

SECTION 2. SPECIAL MEETINGS. The board of directors may call a special meeting of the stockholders for any purpose or purposes and such meeting may be held at such time and place, within or without the State of Delaware, as may be determined by the board of directors. Business transacted at any special meeting of stockholders shall be limited to the purpose or purposes stated in the notice of meeting as required by Section 3 of this Article II. No officer, director nor stockholder shall have the power to call a meeting of stockholders without the authorization of the board of directors.

(The following section was amended by the Board of Directors on July 26, 2007)

SECTION 3. NOTICE. Whenever stockholders are required or permitted to take action at a meeting, written notice stating the place, date and time of the meeting and the means of remote communications, if any, by which stockholders and proxy holders may be deemed to be present and vote at such meeting, and in the case of special meetings, the purpose or purposes of such meeting, shall be given to each stockholder entitled to vote at such meeting not less than 10 nor more than 60 days before the date of the meeting; except that where the matter to be acted on is a merger of the corporation or a sale of all or substantially all of its assets, such notice shall be given not less than 20 nor more than 60 days before the date of the meeting. All such notices shall be delivered, either personally or by mail, by or at the direction of the board of directors, the chief executive officer, or the secretary and, if mailed, such notice shall be deemed to be delivered when deposited with the United States mail, postage prepaid, addressed to the stockholder at the address of the stockholder as the same appears on the records of the corporation. An affidavit of the secretary or an assistant secretary or of the transfer agent or other agent of the corporation that the notice has been given shall in the absence of fraud be prima facie evidence of the facts stated therein.

Notwithstanding the foregoing notice requirements, and unless otherwise prohibited under the General Corporation Law of the State of Delaware, notice shall be effective if by a form of electronic transmission consented to the stockholder or proxy holder to whom such notice is given. Any such consent shall be revocable by such stockholder or proxy holder by written notice to the corporation. Further, any such consent shall be deemed revoked if (i) the corporation is unable to deliver by electronic transmission two consecutive notices given by the corporation in accordance with such consent, and (ii) such inability becomes known to the secretary or assistant secretary of the corporation or to the transfer agent, or other person responsible for giving the notice; provided, however, the inadvertent failure to treat such inability as a revocation shall not invalidate any meeting or other action. Notice given by electronic transmission shall be deemed (i) if by facsimile telecommunication, when directed to a number at which the stockholder has consented to receive notice; (ii) if by electronic mail, when directed to an electronic mail address at which the stockholder has consented to receive notice; (iii) if by a posting on an electronic network together with separate notice to the stockholder of such specific posting, upon the later of (a) such posting, or (b) the giving of such separate notice; and if by any other form of electronic transmission, when directed to the stockholder. An affidavit of the secretary or assistant secretary or of the transfer agent or other agent of the corporation that the notice has been given by a form of electronic transmission shall, in the absence of fraud, be prima facie evidence of the facts stated therein.

Whenever any notice is required to be given under the provisions of the statutes or of the certificate of incorporation or of these by-laws, a waiver thereof in writing, signed by the person or persons entitled to said notice, or a waiver by electronic transmission from the person entitled to notice, whether before or after the time stated therein, shall be deemed equivalent thereto. The written waiver or any waiver by electronic transmission need not specify the business to be transacted at, nor the purpose of, any regular or special meeting of the stockholders. Attendance of a person at a meeting shall constitute a waiver of notice of such meeting, except when the person attends a meeting for the express purpose of objecting at the beginning of the meeting, to the transaction of any business because the meeting is not lawfully called or convened. Attendance at the meeting is not a waiver of any right to object to the consideration of matters required by the General Corporation Law of the State of Delaware to be included in the notice of the meeting but not so included, if such objection is expressly made at the meeting.

Whenever notice is required to be given under the General Corporation Law of the State of Delaware, the certificate of incorporation or these by-laws, to any stockholder, to whom (i) notice of 2 consecutive annual meetings, and all notices of meetings to such person during the period between such 2 consecutive annual meetings, or (ii) all, and at least 2, payments (if sent by first class mail) of dividends or interest on

securities during a 12-month period, have been mailed addressed to such person at such person's address as shown on the records of the corporation and have been returned undeliverable, the giving of such notice to such person shall not be required. Any action or meeting which shall be taken or held without notice to such person shall have the same force and effect as if such notice had been duly given. If any such person shall deliver to the corporation a written notice setting forth such person's then current address, then requirement that notice be given to such person shall be reinstated. The exception to the notice requirement under this section shall not apply to any notice returned as undeliverable if the notice was given by electronic transmission.

(The following section was amended by the Board of Directors on July 26, 2007)

SECTION 4. STOCKHOLDERS LIST. The officer having charge of the stock ledger of the corporation shall make, or cause a third party to prepare and make, at least 10 days before every meeting of the stockholders, a complete list of the stockholders entitled to vote at such meeting arranged in alphabetical order, showing the address of each stockholder and the number of shares registered in the name of each stockholder. Such list shall be open to the examination of any stockholder, for any purpose germane to the meeting, during ordinary business hours, for a period of at least 10 days prior to the meeting: (i) on a reasonably accessible electronic network, provided that the information required to gain access to such list is provided with the notice of the meeting, or (ii) during ordinary business hours, at the principal place of business of the corporation. In the event that the corporation determines to make the list available on an electronic network, the corporation may take reasonable steps to ensure that such information is available only to the stockholders of the corporation. If the meeting is to be held in a place, then the list shall be produced and kept at the time and place of the meeting during the whole time thereof, and may be inspected by any stockholder who is present. If the meeting is to be held solely by means of remote communication, then the list shall also be open to the examination of any stockholder during the whole time of the meeting on a reasonably accessible electronic network, and the information required to access such list shall be provided with the notice of the meeting.

(The following section was amended by the Board of Directors on July 26, 2007)

SECTION 5. QUORUM. The holders of a majority of the outstanding shares of capital stock entitled to vote at a meeting, present in person or represented by proxy, shall constitute a quorum at all meetings of the stockholders, except as otherwise provided by statute or by the certificate of incorporation. For a class or series vote, if applicable, a majority of the class or series, as the case may be, shall constitute a quorum. A quorum that is present to organize a meeting shall not be broken by the subsequent withdrawal of one or more stockholders. If a quorum is not present or represented at any meeting of stockholders, the chairman of the meeting or the holders of a majority of the shares present in person or represented by proxy at the meeting, and entitled to vote at the meeting, may adjourn the meeting from time to time until a quorum shall be present or represented.

SECTION 6. ADJOURNED MEETINGS. When a meeting is adjourned to another time or place, notice need not be given of the adjourned meeting if the time and place thereof are announced at the meeting at which the adjournment is taken. At the adjourned meeting the corporation may transact any business that might have been transacted at the original meeting. If the adjournment is for more than 30 days, or if after the adjournment a new record date is fixed for the adjourned meeting, a notice of the adjourned meeting shall be given to each stockholder of record entitled to vote at the meeting.

SECTION 7. VOTE REQUIRED. When a quorum is present, the affirmative vote of the majority of shares present in person or represented by proxy at the meeting and entitled to vote on the subject matter shall be the act of the stockholders, unless the question is one upon which by express provisions of an

applicable law, certificate of incorporation or these by-laws a different vote is required, in which case such express provision shall govern and control the decision of such question.

SECTION 8. VOTING RIGHTS. Except as otherwise provided by the General Corporation Law of the state of Delaware or by the certificate of incorporation of the corporation or any amendments thereto and subject to Section 10 of this Article II, every stockholder shall at every meeting of the stockholders be entitled to one vote in person or by proxy for each share of common stock held by such stockholder.

(The following section was amended by the Board of Directors on July 26, 2007)

SECTION 9. PROXIES. Each stockholder entitled to vote at a meeting of stockholders may authorize another person or persons to act for such stockholder by proxy. Each proxy shall be in writing executed by the stockholder giving the proxy or the stockholder's duly authorized attorney, or may be given by transmitting or authorizing the transmission of a telegram, cablegram, or other means of electronic transmission to the person who will be the holder of the proxy, to the extent permitted under Section 212 of the General Corporation Law of the State of Delaware. No proxy shall be valid after the expiration of 3 years from its date, unless the proxy provides for a longer period. Unless and until voted, every proxy shall be revocable at the pleasure of the stockholder who executed it or the stockholder's legal representatives or assigns, except in those cases where an irrevocable proxy permitted by statute has been given.

SECTION 10. FIXING A RECORD DATE FOR STOCKHOLDER MEETINGS. In order that the corporation may determine the stockholders entitled to notice of or to vote at any meeting of stockholders or any adjournment thereof, the board of directors may fix a record date, which record date shall not precede the date upon which the resolution fixing the record date is adopted by the board of directors, and which record date shall not be more than 60 nor less than 10 days before the date of such meeting. If no record date is fixed by the board of directors, the record date for determining stockholders entitled to notice of or to vote at a meeting of stockholders shall be the close of business on the next day preceding the day on which notice is given, or if notice is waived, at the close of business on the day next preceding the day on which the meeting is held. A determination of stockholders of record entitled to notice of or to vote at a meeting of stockholders shall apply to any adjournment of the meeting; provided, however, that the board of directors may fix a new record date for the adjourned meeting.

(The following section was added by the Board of Directors on July 18, 1995, and amended by the Board of Directors on July 26, 2007)

SECTION 11. CONDUCT OF MEETINGS. The board of directors shall establish the agenda of each meeting of the stockholders, annual or special, at or prior to the calling thereof. No proposal of any corporate action by any stockholder shall be considered at any meeting of stockholders unless the stockholder who intends to propose such action has delivered a timely written notice of his intention to put such proposal before the meeting to the executive offices of the Corporation. A notice of proposal will be deemed to not be timely unless it has been received by the Corporation within the time limits prescribed by paragraph (a)(iii) of Rule 14a-8 of the Proxy Rules of the Securities and Exchange Commission. The board of directors may determine that a proposal submitted by a stockholder pursuant to this section has insufficient relationship to the business of the Corporation to justify delay, disruption or other interference with the meeting process or that implementation of such proposal would be contrary to applicable law, and upon making such determination, exclude such proposal from consideration at the meeting of stockholders with respect to which such proposal was submitted. The board of directors may, to the extent not prohibited by law, adopt such rules and regulations for the conduct of the meetings of stockholders as it shall deem appropriate. Except as provided in such rules and regulations, or as otherwise determined by the board of directors in advance of a meeting of stockholders, the order of business at all meetings of the stockholders and all matters relating

to the manner of conducting the meeting shall be determined by the chairman of the meeting, whose decisions may be overruled only by the affirmative vote of the majority of shares present in person or represented by proxy at the meeting and entitled to vote on the matter. Meetings shall be conducted in a manner designed to accomplish the business of the meeting in a prompt and orderly fashion and to be fair and equitable to all stockholders, but it shall not be necessary to follow any rules of parliamentary procedure other than as prescribed by the board of directors or by the chairman of the meeting pursuant to this Section 11 of Article II.

ARTICLE III

DIRECTORS

SECTION 1. GENERAL POWERS. The business and affairs of the corporation shall be managed by or under the direction of the board of directors.

SECTION 2. NUMBER, ELECTION AND TERM OF OFFICE. The number of directors which shall constitute the whole board initially shall be 9. Thereafter, the number of directors shall be established from time to time by resolution of the board. The directors shall be elected by a plurality of the votes of the shares present in person or represented by proxy at the meeting and entitled to vote in the election of directors. The directors shall be elected in this manner at the annual meeting of the stockholders, except as provided in Section 4 of this Article III. Each director elected shall hold office until a successor is duly elected and qualified, or until his or her earlier death, resignation, or removal, as hereinafter provided.

(The following paragraph was added by the Board of Directors on July 18, 1995)

At a meeting of stockholders at which directors are to be elected, only persons nominated as candidates shall be eligible for election as directors. Persons may be nominated as candidates by the board of directors or a duly constituted committee thereof, or by any stockholder entitled to vote for the election of directors. Such nominations, if not made by the board of directors or a duly constituted committee thereof, shall be made only by a written notice (a) setting forth (i) the name, age, business address and residence address of each nominee proposed in such notice, (ii) the principal occupation or employment of each such nominee, and (iii) the number of shares of capital stock of the Corporation beneficially owned by each such nominee; (b) signed and verified by the stockholder making such nomination; and (c) delivered to the secretary of the Corporation, together with each such nominee's written acceptance of such nomination and agreement to serve if elected, not less than one hundred twenty (120) days before the first anniversary of the date of the mailing of the notice of the most recently concluded annual meeting, if such nomination is for an election to be held at an annual meeting; provided, however, that if the date of such annual meeting is more than thirty (30) days before or after the first anniversary of the most recently concluded annual meeting, or if such election is to be held at a special meeting, such notice shall be delivered to the Corporation not more than seven (7) days after the date of the notice of such annual or special meeting.

(At the 1996 Annual Meeting of Stockholders, held May 30, 1996 the Stockholders duly adopted a resolution amending these By-laws by adding the following paragraph to the end of this Section 2 of Article III:)

Notwithstanding any other provision set forth in the By-laws of the Company, the board of directors shall be divided into three classes; the term of office of those of the first class to expire at the annual meeting next ensuing; of the second class one year thereafter; of the third class two years thereafter; and at each annual election held after the initial adoption of this by-law by the stockholders and the election of directors

held at the meeting at which this by-law is adopted, directors shall be chosen for a full term of three years, as the case may be, to succeed those whose terms expire. When this by-law is initially adopted by the stockholders, the board of directors shall consist of nine members and each class shall consist of three members. Thereafter, the board of directors may fix the total number of directors constituting the full board of directors and the number of directors in each class, but the total number of directors shall not exceed seventeen (17) nor shall the number of directors in any class exceed six (6). Subject to the foregoing, the classes of directors need not have the same number of members. No reduction in the total number of directors or in the number of directors in any class shall be effective to remove any director or to reduce the term of any director. If the board of directors increases the number of directors in a class, it may fill the vacancy created thereby for the full remaining term of a director in that class even though such term may extend beyond the next annual election. The board of directors may fill any vacancy occurring for any other reason for the full remaining term of the director whose death, resignation or removal caused the vacancy, even though such term may extend beyond the next annual election.

SECTION 3. REMOVAL AND RESIGNATION. Any director or the entire board of directors may be removed at any time by the holders of a majority of the shares then entitled to vote at an election of directors. Whenever the holders of any class or series are entitled to elect one or more directors by the provisions of the corporation's certificate of incorporation, the provisions of this section shall apply, in respect to the removal of a director or directors so elected, to the vote of the holders of the outstanding shares of that class or series and not to the vote of the outstanding shares as a whole. Any director may resign at any time upon written notice to the corporation.

SECTION 4. VACANCIES. Vacancies and newly created directorships resulting from any increase in the authorized number of directors may be filled by a majority of the directors then in office, though less than a quorum, or by a sole remaining director. Each director so chosen shall hold office until a successor is duly elected and qualified, or until his or her earlier death, resignation, or removal, as herein provided.

SECTION 5. COMPENSATION. The board of directors may from time to time fix the compensation of directors for their services in that capacity. The compensation of a director may consist of an annual fee, or a fee for attendance at each regular or special meeting of the board, or any meeting of any committee of the board of which such director is a member, or a combination of fees of both types; provided, that nothing herein contained shall be construed to preclude any director from serving the corporation in any other capacity and receiving compensation therefor. The board also may provide for the reimbursement to any director of expenses incurred in attending any meeting of the board or any committee of the board of which such director is a member.

SECTION 6. ANNUAL MEETINGS. The annual meeting of each newly elected board of directors shall be held without notice immediately after, and at the same place as, the annual meeting of stockholders.

(The following section was amended by the Board of Directors on July 26, 2007)

SECTION 7. OTHER MEETINGS AND NOTICE. Regular meetings, other than the annual meeting, of the board of directors may be held without notice at such time and at such place as shall from time to time be determined by resolution of the board. Special meetings of the board of directors may be called by or at the request of any director on at least 24 hours notice to each director, either personally, by telephone, by mail, by telegraph, or by facsimile or electronic transmission. Notice may be waived in accordance with Section 229 of the General Corporation Law of the State of Delaware.

(The following section was amended by the Board of Directors on July 26, 2007)

SECTION 8. QUORUM, REQUIRED VOTE, AND ADJOURNMENT. A majority of the total number of directors then in office shall constitute a quorum for the transaction of business. The vote of a majority of directors present at a meeting at which a quorum is present shall be the act of the board of directors. If a quorum shall not be present at any meeting of the board of directors, the directors present thereat may adjourn the meeting from time to time, without notice other than announcement at the meeting, until a quorum shall be present. The withdrawal of directors from a meeting at which a quorum was present shall not be deemed to defeat the presence of a quorum.

SECTION 9. COMMITTEES. The board of directors may, by resolution passed by a majority of the whole board, designate one or more committees, each committee to consist of one or more of the directors of the corporation, which to the extent provided in such resolution or these by-laws, shall have and may exercise the powers of the board of directors in the management and affairs of the corporation, except as otherwise limited by law. The board of directors may designate one or more directors as alternate members of any committee, who may replace any absent or disqualified member at any meeting of the committee. Such committee or committees shall have such name or names as may be determined from time to time by resolution adopted by the board of directors. Each committee shall keep regular minutes of its meetings and report the same to the board of directors when required.

SECTION 10. COMMITTEE RULES. Each committee of the board of directors may fix its own rules of procedure and shall hold its meetings as provided by such rules, except as may otherwise be provided by a resolution of the board of directors designating such committee. In the event that a member and that member's alternate, if alternates are designated by the board of directors as provided in Section 9 of this Article III, of such committee is or are absent or disqualified, the member or members thereof present at any meeting and not disqualified from voting, whether or not such member or members constitute a quorum, may unanimously appoint another member of the board of directors to act at the meeting in place of any such absent or disqualified member.

SECTION 11. COMMUNICATIONS EQUIPMENT. Members of the board of directors or any committee thereof may participate in and act at any meeting of such board or committee through the use of a conference telephone or other communications equipment by means of which all persons participating in the meeting can hear each other, and participation in the meeting pursuant to this section shall constitute presence in person at the meeting.

SECTION 12. WAIVER OF NOTICE. Any member of the board of directors or any committee thereof who is present at a meeting shall be conclusively presumed to have waived notice of such meeting, except when such member attends for the express purpose of objecting at the beginning of the meeting to the transaction of any business because the meeting is not lawfully called or convened.

(The following section was amended by the Board of Directors on July 26, 2007)

SECTION 13. ACTION BY WRITTEN CONSENT. Unless otherwise restricted by the certificate of incorporation, any action required or permitted to be taken at any meeting of the board of directors, or of any committee thereof, may be taken without a meeting, if all members of the board or committee, as the case may be, consent thereto in writing or by electronic transmission, and the writing or writings or electronic transmission or transmissions shall be filed with the minutes of proceedings of the board or committee.

ARTICLE IV

OFFICERS

(The following section was amended by the Board of Directors on July 26, 2007)

SECTION 1. NUMBER. The executive officers of the corporation shall be chosen by the board of directors and shall consist of: a chairman of the board, a president, one or more vice-presidents, a secretary, and a treasurer. The board of directors may also choose such other officers and assistant officers as it may deem necessary or desirable, who shall hold their offices for such terms and shall exercise such powers and perform such duties as shall be determined from time to time by the Board of Directors. The chairman of the board or vice chairman of the board shall be selected among the directors, but no other executive officer need be a member of the board. Any number of offices may be held by the same person. In its discretion, the board of directors may choose not to fill any office for any period as it may deem advisable.

(The following section was amended by the Board of Directors on July 26, 2007)

SECTION 2. ELECTION AND TERM OF OFFICE. The officers of the corporation shall be elected by the board of directors, and each officer shall hold office until a successor is duly elected by the board of directors, or until his or her earlier death, resignation, or removal, as hereinafter provided.

SECTION 3. REMOVAL. Any officer or agent elected by the board of directors may be removed for cause or without cause by the board of directors, or by the chairman of the board or the president acting under authority delegated to him by the board, provided that any such removal shall be without prejudice to the contract rights, if any, of the person so removed.

SECTION 4. VACANCIES. Any vacancy occurring in any office because of death, resignation, removal, disqualification, or otherwise may be filled by the board of directors.

SECTION 5. COMPENSATION. Compensation of all officers shall be fixed by the board of directors and no officer shall be prevented from receiving such compensation by virtue of his or her also being a director of the corporation.

(The following section was amended by the Board of Directors on July 26, 2007)

SECTION 6. CHAIRMAN OF THE BOARD AND VICE CHAIRMAN OF THE BOARD. The chairman of the board, if any, shall preside at all meetings of the board of directors and of the stockholders at which the chairman shall be present. The chairman shall have and may exercise such powers as are, from time to time, assigned to the chairman by the board of directors and as may be provided by law. In the absence of the chairman of the board, the vice chairman of the board, if any, shall preside at all meetings of the board of directors and of the stockholders at which the vice chairman shall be present. The vice chairman shall have and may exercise such powers as are, from time to time, assigned to such person by the board of directors and as may be provided by law.

(The following section was amended by the Board of Directors on July 26, 2007)

SECTION 7. PRESIDENT. The president shall be the chief executive officer of the corporation unless such title is assigned to another officer of the corporation; in the absence of a chairman and vice chairman of the board, the president shall preside as the chairman of meetings of the stockholders and the board of directors; and the president shall (subject to the authority of the chief executive officer, if any) have general and active management of the business of the corporation and shall see that all orders and resolutions of the board of directors are carried into effect.

SECTION 8. VICE-PRESIDENTS. The vice-president, or if there shall be more than one, the vice-presidents in the order determined by the board of directors shall, in the absence or disability of the president,

act with all of the powers and be subject to all restrictions of the president. The vice-presidents also shall perform such other duties and have such other powers as the board of directors, the chairman of the board, the president, or these by-laws may, from time to time, prescribe.

SECTION 9. SECRETARY AND ASSISTANT SECRETARIES. The secretary shall attend all meetings of the board of directors, all meetings of the committees thereof, and all meetings of the stockholders, and record all such proceedings of such meetings in a book to be kept for that purpose. The assistant secretary, or if there be more than one, the assistant secretaries in the order determined by the chairman of the board, shall, in the absence or disability of the secretary, perform the duties of the secretary.

SECTION 10. TREASURER AND ASSISTANT TREASURERS. The treasurer shall have the custody of the corporate funds and securities; shall keep full and accurate accounts of receipts and disbursements thereof; shall deposit all moneys and other valuable effects in the name of the corporation; shall cause the funds of the corporation to be disbursed when such disbursements have been duly authorized. If required by the board of directors, the treasurer and each assistant treasurer shall give the corporation a bond for such term, in such sums and with such sureties as shall be satisfactory to the board of directors for the faithful performance of the duties of the office of treasurer. The assistant treasurer, or if there shall be more than one, the assistant treasurers in the order determined by the chairman of the board, shall in the absence or disability of the treasurer, perform the duties of the treasurer.

SECTION 11. OTHER OFFICERS, ASSISTANT OFFICERS, AND AGENTS. Officers, assistant officers and agents, if any, shall have such authority and perform such duties as may from time to time be prescribed by resolution of the board of directors.

SECTION 12. ABSENCE OR DISABILITY OF OFFICERS. In the case of the absence or disability of any officer of the corporation and of any person hereby authorized to act in such officer's place during such officer's absence or disability, the chairman of the board or the president may delegate the powers and duties of such officer to any other officer.

ARTICLE V

INDEMNIFICATION OF OFFICERS, DIRECTORS AND OTHERS

SECTION 1. INDEMNIFICATION. The corporation shall indemnify any person who was or is a party or is threatened to be made a party to:

(a) any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of the corporation) by reason of the fact that he is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by him in connection with such action, suit or proceeding if he acted in good faith and in a manner he reasonably believed to be in or not opposed to the best interests of the corporation, and with respect to any criminal action or proceeding, had no reasonable cause to believe his conduct was unlawful; the termination of any action, suit or proceeding by judgment, order, settlement, conviction, or upon a plea of nolo contendere or its equivalent, shall not, of itself, create a presumption that the person did not act in good faith and in a manner which he reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had reasonable cause to believe that his conduct was unlawful; or

(b) any threatened, pending or completed action or suit by or in the right of the corporation to procure a judgment in its favor by reason of the fact that he is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise against expenses (including attorneys' fees) actually and reasonably incurred by him in connection with the defense or settlement of such action or suit if he acted in good faith and in a manner he reasonably believed to be in or not opposed to the best interests of the corporation and except that no indemnification shall be made in respect of any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that the Court of Chancery or the court in which such action or suit was brought shall determine upon application that, despite the adjudication of liability but in view of all the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which the Court of Chancery or such other court shall deem proper.

To the extent that a director, officer, employee or agent of the corporation has been successful on the merits or otherwise in defense of any action, suit or proceeding referred to in subsections (a) and (b) above, or in defense of any claim, issue or matter therein, he shall be indemnified against expenses (including attorneys' fees) actually and reasonably incurred by him in connection therewith.

SECTION 2. STANDARD OF CONDUCT. Any indemnification under subsections (a) and (b) of Section 1 of this Article V (unless ordered by a court) shall be made by the corporation only as authorized in the specific case upon a determination that indemnification of the director, officer, employee or agent is proper in the circumstances because he has met the applicable standard of conduct set forth in said subsections (a) and (b). Such determination shall be made (1) by the board of directors by a majority vote of a quorum consisting of directors who were not parties to such action, suit or proceeding, or (2) if such a quorum is not obtainable, or, even if obtainable a quorum of disinterested directors so directs, by independent legal counsel in a written opinion, or (3) by the stockholders.

SECTION 3. PAYMENT OF EXPENSES. Expenses (including attorneys' fees) incurred by an officer or director in defending any civil, criminal, administrative, or investigative action, suit or proceeding shall be paid by the corporation in advance of the final disposition of such action, suit or proceeding upon receipt of an undertaking by or on behalf of such director or officer to repay such amount if it shall ultimately be determined that he is not entitled to be indemnified by the corporation as authorized in this Article V. Such expenses (including attorneys' fees) incurred by other employees and agents may be so paid upon such terms and conditions, if any, as the board of directors deems appropriate.

SECTION 4. NOT EXCLUSIVE. The indemnification and advancement of expenses provided by, or granted pursuant to, the provisions of this Article V shall not be deemed exclusive of any other rights to which those seeking indemnification or advancement of expenses may be entitled under the certificate of incorporation, or any agreement, vote of stockholders or disinterested directors or otherwise, both as to action in his official capacity and as to action in another capacity while holding such office.

SECTION 5. INSURANCE. The corporation may purchase and maintain insurance on behalf of any person who is a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise against any liability asserted against him and incurred by him in any such capacity, or arising out of his status as such, whether or not the corporation would have the power to indemnify him against such liability under the provisions of this section.

SECTION 6. DEFINITIONS.

(a) For purposes of this Article V, references to "the corporation" shall include, in addition to the corporation, any constituent corporation (including any constituent of a constituent) absorbed in a consolidation or merger which, if its separate existence had continued, would have had power and authority to indemnify its directors, officers, and employees or agents, so that any person who is or was a director, officer, employee or agent of such constituent corporation or is or was serving at the request of such constituent corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, shall stand in the same position under the provisions of this Article V with respect to the resulting or surviving corporation as he would have with respect to such constituent corporation if its separate existence had continued.

(b) For purposes of this Article V, references to "other enterprises" shall include employee benefit plans; references to "fines" shall include any excise taxes assessed on a person with respect to an employee benefit plan; and references to "serving at the request of the corporation" shall include any service as a director, officer, employee or agent of the corporation which imposes duties on, or involves services by, such director, officer, employee, or agent with respect to an employee benefit plan, its participants, or beneficiaries; and a person who acted in good faith and in a manner he reasonably believed to be in the interest of the participants and beneficiaries of an employee benefit plan shall be deemed to have acted in a manner "not opposed to the best interests of the corporation" as referred to in this Article V.

SECTION 7. CONTRACTUAL NATURE. This Article V shall be deemed to be a contract between the corporation and each director and officer who serves as such at any time while this Article V is in effect, and any repeal or modification thereof shall not affect any rights or obligations then existing with respect to any state of facts then or theretofore existing or any action, suit or proceeding theretofore or thereafter brought based in whole or in part upon such state of facts. The indemnification and advancement of expenses provided by, or granted pursuant to, this Article V shall, unless otherwise provided when authorized or ratified, continue as to a person who has ceased to be a director, officer, employee or agent and shall inure to the benefit of the heirs, executors and administrators of such a person.

ARTICLE VI

CERTIFICATES OF STOCK

(The following section was amended by the Board of Directors on July 26, 2007)

SECTION 1. FORM. Every holder of stock in the corporation shall be entitled to have a certificate, unless and until the Board of Directors adopts a resolution permitting shares to be uncertificated, signed by, or in the name of the corporation by, the chairman of the board of directors or the president or a vice-president, and the secretary or an assistant secretary, or the treasurer or an assistant treasurer of the corporation, certifying the number of shares owned by such holder of the corporation. If such a certificate is countersigned (1) by a transfer agent or an assistant transfer agent other than the corporation or one of its employees or (2) by a registrar, other than the corporation or one of its employees, the signature of any such chairman of the board of directors, president, vice-president, secretary, assistant secretary, treasurer or assistant treasurer may be facsimiles. In case any officer or officers who have signed, or whose facsimile signature or signatures have been used on, any such certificate or certificate, shall cease to be such officer or officers of the corporation whether because of death, resignation, or otherwise before such certificate or certificates have been delivered by the corporation, such certificate or certificates may nevertheless be issued and delivered as though the person or persons who signed such certificate or certificates or whose facsimile signature or signatures have been used thereon had not ceased to be such officer or officers of the corporation. The board of directors

may appoint a bank or trust company organized under the laws of the United States or any state thereof to act as its transfer agent or registrar, or both in connection with the transfer of any class or series of securities of the corporation.

SECTION 2. LOST CERTIFICATES. The board of directors may direct a new certificate or certificates to be issued in place of any certificate or certificates previously issued by the corporation alleged to have been lost, stolen, or destroyed, upon the making of an affidavit of that fact by the person claiming the certificate of stock to be lost, stolen, or destroyed. When authorizing such issue of a new certificate or as a condition precedent to the issuance thereof, the board of directors may require the owner of such lost, stolen, or destroyed certificate or certificates, or the owner's representative, to give the corporation a bond sufficient to indemnify the corporation against any claim that may be made against the corporation on account of the loss, theft, or destruction of any such certificate or the issuance of such new certificate.

SECTION 3. FIXING A RECORD DATE FOR PURPOSES OTHER THAN FOR STOCKHOLDER MEETINGS. In order that the corporation may determine the stockholders entitled to receive payment of any dividend or other distribution or allotment or any rights or the stockholders entitled to exercise any rights in respect of any change, conversion, or exchange of stock, or for the purposes of any other lawful action, the board of directors may fix a record date, which record date shall not precede the date upon which the resolution fixing the record date is adopted, and which record date shall be not more than 60 days prior to such action. If no record date is fixed, the record date for determining stockholders for any such purpose shall be at the close of business on the day on which the board of directors adopts the resolution relating thereto.

(The following section was added by the Board of Directors on July 26, 2007)

SECTION 4. REGISTERED STOCKHOLDERS. The corporation shall be entitled to recognize the exclusive right of a person registered on its books as the owner of shares to receive dividends and to vote as such owner a person registered on its books as the owner of shares, and shall not be bound to recognize any equitable or other claim to or interest in such share or shares on the part of any other person, whether or not it shall have express or other notice thereof, except as otherwise provided by the laws of Delaware.

ARTICLE VII

GENERAL PROVISIONS

SECTION 1. FISCAL YEAR. The fiscal year of the corporation shall end on December 31 unless otherwise fixed by resolution of the board of directors.

(The following section was amended by the Board of Directors on July 26, 2007)

SECTION 2. CORPORATE SEAL. The board of directors may adopt a corporate seal in such proper form as it may prescribe from time to time. The seal may be used by causing it or a facsimile thereof to be impressed or affixed or reproduced or otherwise.

SECTION 3. VOTING SECURITIES OWNED BY THE CORPORATION. Voting securities in any other corporation held by the corporation shall be voted by the chairman of the board or the president, unless the board of directors specifically confers authority to vote with respect thereto, which authority may be general or confined to specific instances, upon some other person or officer. Any person authorized to vote securities shall have the power to appoint proxies, with general power of substitution.

SECTION 4. INSPECTION OF BOOKS AND RECORDS. Any stockholder of record, in person or by attorney or other agent, shall, upon written demand under oath stating the purpose thereof, have the right during the usual hours for business to inspect for any proper purpose the corporation's stock ledger, a list of its stockholders, and its other books and records, and to make copies or extracts therefrom. A proper purpose shall mean any purpose reasonably related to such person's interest as a stockholder. In every instance where an attorney or other agent shall be the person who seeks the right to inspection, the demand under oath shall be accompanied by a power of attorney or such other writing that authorizes the attorney or other agent to so act on behalf of the stockholder. The demand under oath shall be directed to the corporation at its principal place of business.

SECTION 5. SECTION HEADINGS. Section headings in these by-laws are for convenience of reference only and shall not be given any substantive effect in limiting or otherwise construing any provision herein.

SECTION 6. INCONSISTENT PROVISIONS. In the event that any provision of these by-laws is or becomes inconsistent with any provision of the certificate of incorporation, the General Corporation Law of the state of Delaware, or any other applicable law, the provision of these by-laws shall not be given any effect to the extent of such inconsistency but shall otherwise be given full force and effect.

(The following section was added by the Board of Directors on November 7, 2013)

SECTION 7. Unless the corporation consents in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for (i) any derivative action or proceeding brought on behalf of the corporation, (ii) any action asserting a claim of breach of a fiduciary duty owed by any director, officer or other employee of the corporation to the corporation or the corporation's stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, or (iv) any action asserting a claim governed by the internal affairs doctrine. Any person or entity purchasing or otherwise acquiring any interest in shares of capital stock of the corporation shall be deemed to have notice of and consented to the provisions of this Section 7 of Article VII of the corporations bylaws.

ARTICLE VIII

AMENDMENTS

These by-laws may be amended, altered or repealed and new by-laws adopted at any meeting of the board of directors by a majority vote. The fact that the power to adopt, amend, alter or repeal the by-laws has been conferred upon the board of directors shall not divest the stockholders of the same powers.

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Mark J. Pykett, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Navidea Biopharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

November 12, 2013

/s/ Mark J. Pykett

Mark J. Pykett, V.M.D., Ph.D.
Chief Executive Officer

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Brent L. Larson, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Navidea Biopharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

November 12, 2013

/s/ Brent L. Larson

Brent L. Larson

Executive Vice President and Chief Financial Officer

**CERTIFICATION OF PERIODIC FINANCIAL REPORT PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002, 18 U.S.C. SECTION 1350**

The undersigned hereby certifies that he is the duly appointed and acting Chief Executive Officer of Navidea Biopharmaceuticals, Inc. (the "Company") and hereby further certifies as follows:

(1) The periodic report containing financial statements to which this certificate is an exhibit fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the periodic report to which this certificate is an exhibit fairly presents, in all material respects, the financial condition and results of operations of the Company.

In witness whereof, the undersigned has executed and delivered this certificate as of the date set forth opposite his signature below.

November 12, 2013

/s/ Mark J. Pykett

Mark J. Pykett, V.M.D., Ph.D.

Chief Executive Officer

**CERTIFICATION OF PERIODIC FINANCIAL REPORT PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002, 18 U.S.C. SECTION 1350**

The undersigned hereby certifies that he is the duly appointed and acting Chief Financial Officer of Navidea Biopharmaceuticals, Inc. (the "Company") and hereby further certifies as follows:

(1) The periodic report containing financial statements to which this certificate is an exhibit fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the periodic report to which this certificate is an exhibit fairly presents, in all material respects, the financial condition and results of operations of the Company.

In witness whereof, the undersigned has executed and delivered this certificate as of the date set forth opposite his signature below.

November 12, 2013

/s/ Brent L. Larson

Brent L. Larson

Executive Vice President and Chief Financial Officer