NAVIDEA BIOPHARMACEUTICALS, INC.
Form 10-Q
November 13, 2012

THIS DOCUMENT IS A COPY OF THE QUARTERLY REPORT ON FORM 10-Q FILED ON NOVEMBER 13, 2012 PURSUANT TO A RULE 201 TEMPORARY HARDSHIP EXEMPTION

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2012

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

For the transition period from _____ to _____

Commission File Number: 001-35076

NAVIDEA BIOPHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

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

425 Metro Place North, Suite 450, Dublin, Ohio	43017-1367
(Address of principal executive offices)	(Zip Code)

(614) 793-7500
(Registrant's telephone number, including area code)

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

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

Yes x No ¨

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

Yes x No ¨

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

Large accelerated filer ¨	Accelerated filer x
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company ¨

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

Yes ¨ No x

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date: 107,390,632 shares of common stock, par value $.001 per share (as of the close of business on November 2,

2012).

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, 2012 (unaudited)	December 31, 2011
Current assets:		
Cash	$ 11,211,170	$ 28,644,004
Accounts receivable, net	22,775	15,794
Inventory, net	641,000	821,549
Prepaid expenses and other	298,912	565,174
Total current assets	12,173,857	30,046,521
Property and equipment	1,997,390	1,441,229
Less accumulated depreciation and amortization	1,055,251	977,960
	942,139	463,269
Patents and trademarks	112,562	106,592
Less accumulated amortization	21,766	21,171
	90,796	85,421
Other assets	400,926	598,709
Total assets	$ 13,607,718	$ 31,193,920

Continued

Navidea Biopharmaceuticals, Inc. and Subsidiaries,

Consolidated Balance Sheets, continued

LIABILITIES AND STOCKHOLDERS' EQUITY	September 30, 2012 (unaudited)	December 31, 2011
Current liabilities:		
Accounts payable	$1,970,569	$681,754
Accrued liabilities and other	2,103,133	2,097,786
Note payable to investor, current, net of discount of $224,701	2,425,973	—
Derivative liabilities, current	509,687	568,930
Total current liabilities	7,009,362	3,348,470
Note payable to investor, net of discounts of $135,186 and $543,612, respectively	3,593,660	6,456,388
Other liabilities	250,588	257,315
Total liabilities	10,853,610	10,062,173
Commitments and contingencies		
Stockholders' equity:		
Preferred stock; $.001 par value; 5,000,000 shares authorized; 6,020 and 9,083 Series B shares and 1,000 Series C shares issued and outstanding at September 30, 2012 and December 31, 2011, respectively	7	10
Common stock; $.001 par value; 200,000,000 shares authorized; 107,370,632 and 95,398,961 shares issued and outstanding at September 30, 2012 and December 31, 2011, respectively	107,371	95,399
Additional paid-in capital	270,001,531	266,393,645
Accumulated deficit	(267,354,801)	(245,357,307)
Total stockholders' equity	2,754,108	21,131,747
Total liabilities and stockholders' equity	$13,607,718	$31,193,920

See accompanying notes to unaudited consolidated financial statements

Navidea Biopharmaceuticals, Inc. and Subsidiaries

Consolidated Statements of Operations and Comprehensive Loss

(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Revenue	$—	$255,632	$71,931	$597,729
Operating expenses:				
Research and development	6,127,546	3,858,141	12,547,373	8,159,992
Selling, general and administrative	2,941,851	2,870,603	8,487,318	7,499,454
Total operating expenses	9,069,397	6,728,744	21,034,691	15,659,446
Loss from operations	(9,069,397)	(6,473,112)	(20,962,760)	(15,061,717)
Other income (expense):				
Interest income	4,947	7,362	22,850	13,865
Interest expense	(315,262)	(564)	(930,338)	(3,229)
Change in derivative liabilities	283,731	7,208	6,842	(956,933)
Other	(2,619)	(709)	(59,088)	(1,807)
Total other (expense) income, net	(29,203)	13,297	(959,734)	(948,104)
Loss before income taxes	(9,098,600)	(6,459,815)	(21,922,494)	(16,009,821)
Benefit from income tax	—	6,403,928	—	6,403,928
Loss from continuing operations	(9,098,600)	(55,887)	(21,922,494)	(9,605,893)
Discontinued operations, net of tax effect:				
Gain on sale – GDS Business	—	20,108,502	—	19,498,798
(Loss) income from operations	—	(220,682)	—	3,328,009
Net (loss) income and comprehensive (loss)	(9,098,600)	19,831,933	(21,922,494)	13,220,914
Preferred stock dividends	(25,000)	(25,000)	(75,000)	(75,000)
Net (loss) income and comprehensive (loss) income attributable to common stockholders	$(9,123,600)	$19,806,933	$(21,997,494)	$13,145,914
(Loss) income per common share (basic and diluted):				
Continuing operations	$(0.09)	$—	$(0.23)	$(0.11)
Discontinued operations	$—	$0.21	$—	$0.26

Attributable to common stockholders	$(0.09)	$0.21	$(0.23)	$0.15
Weighted average shares outstanding:				
Basic and diluted	102,332,983	93,070,235	97,042,832	89,410,150

See accompanying notes to unaudited consolidated financial statements.

Navidea Biopharmaceuticals, Inc. and Subsidiaries

Consolidated Statement of Stockholders' Equity

(unaudited)

	Preferred Stock		Common Stock		Additional Paid-In	Accumulated	
	Shares	Amount	Shares	Amount	Capital	Deficit	Total
Balance, December 31, 2011	10,083	$ 10	95,398,961	$95,399	$266,393,645	$(245,357,307)	$21,131,747
Issued restricted stock	—	—	435,000	435	—	—	435
Cancelled restricted stock	—	—	(4,500)	(5)	5	—	—
Issued stock upon exercise of stock options, net	—	—	1,225,271	1,226	742,069	—	743,295
Cancelled stock upon repurchase from executives	—	—	(37,500)	(37)	(100,838)	—	(100,875)
Issued stock to 401(k) plan	—	—	17,390	17	50,255	—	50,272
Issued stock upon exercise of warrants, net	—	—	20,000	20	58,581	—	58,601
Conversion of Series B preferred stock to common stock	(3,063)	(3)	10,016,010	10,016	(10,013)	—	—
Issued stock for payment of sublicense fee	—	—	300,000	300	1,145,700	—	1,146,000
Stock compensation expense	—	—	—	—	1,722,127	—	1,722,127
Preferred stock dividends	—	—	—	—	—	(75,000)	(75,000)
Net loss	—	—	—	—	—	(21,922,494)	(21,922,494)
Balance, September 30, 2012	7,020	$ 7	107,370,632	$107,371	$270,001,531	$(267,354,801)	$2,754,108

See accompanying notes to unaudited consolidated financial statements.

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Navidea Biopharmaceuticals, Inc. and Subsidiaries

Consolidated Statements of Cash Flows

(unaudited)

	Nine Months Ended September 30,	
	2012	2011
Cash flows from operating activities:		
Net (loss) income	$(21,922,494)	$13,220,914
Adjustments to reconcile net (loss) income to net cash used in operating activities:		
Depreciation and amortization	139,424	150,802
Loss on disposal and abandonment of assets	—	18,503
Amortization of debt discount and debt offering costs	406,982	—
Stock compensation expense	1,722,127	3,073,074
Change in derivative liabilities	(6,842)	956,933
Issuance of common stock to 401(k) plan	50,272	61,971
Gain on sale of discontinued operations, before income taxes	—	(25,172,041
Issuance of common stock for payment of sublicense fee	1,146,000	—
Changes in operating assets and liabilities:		
Accounts receivable	2,189	(278,473)
Inventory	180,549	(75,942)
Prepaid expenses and other assets	231,618	195,482
Accounts payable	1,289,615	74,168
Accrued liabilities and other liabilities	155,864	1,316,733
Deferred revenue	—	162,830
Net cash used in operating activities	(16,604,696)	(6,295,046)
Cash flows from investing activities:		
Purchases of equipment	(617,699)	(94,863)
Proceeds from sales of equipment	—	1,000
Proceeds from sale of discontinued operations – GDS Business	—	30,000,000
Payments of costs to sell discontinued operations – GDS Business	—	(2,761,615)
Patent and trademark costs	(5,969)	(53,294)
Net cash (used in) provided by investing activities	(623,668)	27,091,228
Cash flows from financing activities:		
Proceeds from issuance of common stock	758,695	7,134,037
Payment for common stock repurchased from executives	(100,875)	—
Payment of tax withholdings related to stock-based compensation	(8,765)	(2,441,496)
Payment of preferred stock dividends	(75,000)	(75,000)
Payment of debt issuance costs	(153,949)	—
Principal payment on notes payable	(620,480)	(62,411)
Payments under capital leases	(4,096)	(7,358)
Net cash (used in) provided by financing activities	(204,470)	4,547,772

Net (decrease) increase in cash	(17,432,834)	25,343,954
Cash, beginning of period	28,644,004	6,420,506
Cash, end of period	$11,211,170	$31,764,460

See accompanying notes to unaudited consolidated financial statements.

1. Summary of Significant Accounting Policies

a. **Basis of Presentation:** The information presented as of September 30, 2012, and for the three-month and nine-month periods ended September 30, 2012 and September 30, 2011, 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, 2012, 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, 2011, 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.

In 2011, the Company's Board of Directors and our stockholders approved the sale of our line of neoprobe® GDS gamma detection systems (the GDS Business) as well as the disposal of the related extended warranty contracts to Devicor Medical Products, Inc. (Devicor).

In 2009, the Company's Board of Directors decided to discontinue the operations of, and attempt to sell, our Cardiosonix subsidiary. The operations of Cardiosonix were effectively wound down in 2011.

Our consolidated balance sheet and statements of operations have been reclassified for 2011 and are presented to reflect the GDS Business and Cardiosonix as discontinued operations, as required. Cash flows associated with the operation of the GDS Business and Cardiosonix have been combined within operating, investing and financing cash flows, as appropriate, in our consolidated statements of cash flows. See Note 2.

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. In addition, we considered non-performance risk and determined that such risk is minimal. See Note 3.

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) Note payable to investor: The carrying value of our debt at September 30, 2012 and December 31, 2011 is presented as the face amount of the note less unamortized discounts. At September 30, 2012, the fair value of the note payable to investor is approximately $6.4 million, which approximates face value. See Note 8.

(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, 2012 and December 31, 2011 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 derivative liabilities in the statements of operations. See Note 10.

2. Discontinued Operations

In 2009, the Company's Board of Directors decided to discontinue the operations of our Cardiosonix subsidiary and hold the assets for sale, based on the determination that the blood flow measurement device segment was no longer considered a strategic initiative of the Company. The operations of Cardiosonix were effectively wound down during 2011.

In 2011, our Board of Directors and our stockholders approved the sale of the GDS Business as well as the disposal of the related extended warranty contracts to Devicor for a net purchase price of $30.3 million.

As a result, we reclassified revenues and expenses related to the GDS Business and our Cardiosonix subsidiary to discontinued operations. The following amounts have been segregated from continuing operations and included in discontinued operations in the consolidated statements of operations:

	Three Months Ended September 30, 2011	Nine Months Ended September 30, 2011
Net sales	$ 1,785,540	$ 7,522,474
Cost of goods sold	560,909	2,323,858

Gross profit	1,224,631	5,198,616
Operating expenses:		
Research and development	293,990	572,209
Selling, general and administrative	149,799	296,652
Total operating expenses	443,789	868,861
Other expense, net	(363)	(585)
Income taxes	(1,001,161)	(1,001,161)
(Loss) income from discontinued operations	$ (220,682)	$ 3,328,009

3. Fair Value Hierarchy

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, 2012

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, 2012
Liabilities:				
Derivative liabilities related to warrants, current	$ —	$ 509,687	$ —	$ 509,687

Liabilities Measured at Fair Value on a Recurring Basis as of December 31, 2011

Description	Quoted Prices in Active Markets for Identical Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Balance as of December 31, 2011
Liabilities:				
Derivative liabilities related to warrants, current	$ —	$ 568,930	$ —	$ 568,930

There were no Level 1 liabilities outstanding at any time during the three-month or nine-month periods ended September 30, 2012 and 2011. There were no transfers in or out of our Level 2 liabilities during the three-month or nine-month periods ended September 30, 2012. A total of $1,978,818 of our Level 2 liabilities were reclassified to equity related to modifying certain outstanding warrants to remove the language that had previously required them to be classified as derivative liabilities during the nine-month period ended September 30, 2011.

4. Stock-Based Compensation

At September 30, 2012, 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 day prior to 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 90 days from 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 using the straight-line method over the vesting period. Restricted shares may vest based on the passage of time, or they may vest 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, 2012 and 2011, our total stock-based compensation expense was approximately $588,000 and $1.8 million, respectively. For the nine-month periods ended September 30, 2012 and 2011, our total stock-based compensation expense was approximately $1.7 million and $3.1 million, respectively. Stock-based compensation expense for the first nine months of 2011 included approximately $1.5 million of expense related to the separation of our former President and CEO. (See Note 7.) We have not recorded any income tax benefit related to stock-based compensation in any of the three-month or nine-month periods ended September 30, 2012 and 2011.

A summary of the status of our stock options as of September 30, 2012, and changes during the nine-month period then ended, is presented below:

	Nine Months Ended September 30, 2012			
	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value
Outstanding at beginning of period	3,315,000	$ 1.02		
Granted	1,127,527	3.22		
Exercised	(1,232,001)	0.62		
Forfeited	(10,499)	2.00		
Expired	(9,000)	1.73		
Outstanding at end of period	3,191,027	$ 1.95	6.9 years	$3,351,226
Exercisable at end of period	1,600,772	$ 1.01	4.8 years	$2,877,662

A summary of the status of our unvested restricted stock as of September 30, 2012, and changes during the nine-month period then ended, is presented below:

	Nine Months Ended September 30, 2012	
	Number of Shares	Weighted Average Grant-Date Fair Value
Unvested at beginning of period	1,556,000	$ 2.48
Granted	385,000	3.16
Vested	(30,000)	2.86
Forfeited	—	—
Expired	—	—
Unvested at end of period	1,911,000	$ 2.61

As of September 30, 2012, there was approximately $2.3 million of total unrecognized compensation expense related to unvested stock-based awards, which we expect to recognize over remaining weighted average vesting terms of 1.9 years.

5. 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 reconciliation of the weighted average number of common shares outstanding to those used to compute basic and diluted earnings (loss) per share for the three-month and nine-month periods ended September 30, 2012 and 2011:

	Basic and Diluted Earnings Per Share			
	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Outstanding shares	107,370,632	95,110,527	107,370,632	95,110,527
Effect of weighting changes in outstanding shares	(3,126,649)	(479,792)	(8,416,800)	(4,139,877)
Unvested restricted stock	(1,911,000)	(1,560,500)	(1,911,000)	(1,560,500)
Adjusted shares	102,332,983	93,070,235	97,042,832	89,410,150

Earnings (loss) per common share for the three-month and nine-month periods ended September 30, 2012 and 2011 excludes the effects of 45.0 million and 54.4 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, 1,911,000 and 1,560,500 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, 2012 and 2011, respectively, because such inclusion would be anti-dilutive.

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6. Inventory, net

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. From time to time, we capitalize certain inventory costs associated with our Lymphoseek® product prior to regulatory approval and product launch based on management's judgment of probable future commercial use and net realizable value of the inventory. We could be required to permanently write down previously capitalized costs related to pre-approval or pre-launch inventory upon a change in such judgment, due to a denial or delay of approval by regulatory bodies, a delay in commercialization, slower than expected sales, or other potential factors. Conversely, our gross margins may be favorably impacted if some or all of the inventory previously expensed becomes available and is used for commercial sale. During the nine-month periods ended September 30, 2012 and 2011, we capitalized $525,000 and $213,000, respectively, of inventory costs associated with our Lymphoseek product. During the three-month periods ended September 30, 2012 and 2011, we did not capitalize any such costs. During the three-month and nine-month periods ended September 30, 2012, we wrote off $278,000 and $378,000, respectively, of previously capitalized Lymphoseek inventory due to its use in previously unanticipated product development activities. During the three-month and nine-month periods ended September 30, 2011, we did not write off any such costs.

The components of net inventory as of September 30, 2012 and December 31, 2011, net of reserves of $327,000 and $0, respectively, are as follows:

	September 30, 2012 (unaudited)	December 31, 2011
Pharmaceutical materials	$ 641,000	$ 482,000
Pharmaceutical work-in-process	—	339,549
Total	$ 641,000	$ 821,549

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, historical and 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 based on the potential for the delay in U.S. regulatory approval to impact the timing of future commercial use of the specific lots previously capitalized.

7. Separation of Former CEO

In March 2011, Navidea announced the departure of our then-current President and CEO, David C. Bupp, effective April 15, 2011. The following table summarizes accrued expenses as of September 30, 2012 and December 31, 2011, including employer payroll tax obligations, related to the provisions of Mr. Bupp's separation agreement:

	September 30, 2012 (unaudited)	December 31, 2011
Separation	$ —	$ 180,074
Pro-rated 2011 bonus	—	60,870
Estimated continuing healthcare coverage	27,633	61,875
	$ 27,633	$ 302,819

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8. Convertible Securities

In May 2011, Platinum-Montaur Life Sciences, LLC (Montaur) converted 917 shares of their Series B Convertible Preferred Stock (the Series B) into 2,998,590 shares of our common stock under the terms of the Series B. In July 2012, Montaur converted 3,063 shares of their Series B into 10,016,010 shares of our common stock under the terms of the Series B. As of September 30, 2012, there are 6,020 shares of Series B outstanding which are convertible into 19,685,400 shares of our common stock.

In December 2011, we executed a Loan and Security Agreement (the Loan Agreement) with Hercules Technology II, L.P. (Hercules), providing for a maximum borrowing of $10 million by the Company in two advances. Pursuant to the Loan Agreement, we issued Hercules: (1) a Secured Term Promissory Note in the principal amount of $7,000,000 (the First Advance), 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% (effective interest rate at September 30, 2012 was 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). Additionally, the Loan Agreement provided Navidea with the option to draw a second advance in the principal amount of $3,000,000 if certain conditions were met by June 30, 2012. Such conditions were not met and Hercules no longer has an obligation to provide the additional $3,000,000. The Loan Agreement provided for an interest-only period beginning on December 29, 2011 and expiring on July 1, 2012. 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. As such, a portion of the principal, net of related discounts, has been classified as a current liability as of September 30, 2012. The outstanding balance of the debt is due December 1, 2014. Navidea has the option to pay up to $1.5 million of the principal amount of the debt in stock at a fixed conversion price of $2.77, subject to certain conditions. In addition, Hercules has the option to elect payment for up to another $1.5 million of the principal amount of the debt by conversion at a fixed conversion price of $2.77.

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 provide certain information, such as financial statements and budgets, on a periodic basis. As of September 30, 2012, we were in compliance with all such covenants.

In accordance with current accounting standards, Hercules’ option to convert up to $1.5 million of the debt into stock was evaluated and determined to be a beneficial conversion feature. The beneficial conversion feature of $24,888 was recorded as a discount on the First Advance based on the market price of the Company’s stock on the date of the Loan Agreement. In addition, the Series GG Warrant was accounted for as a liability at origination due to the existence of certain provisions in the instrument which will remain in effect for the first 365 days the warrant is outstanding.

During the three-month and nine-month periods ended September 30, 2012, we recorded interest expense of $147,000 and $407,000, respectively, related to amortization of the debt discounts and deferred financing costs related to our

convertible note. We recorded no such interest expense during the three-month and nine-month periods ended September 30, 2011. During the third quarter of 2012, we paid $620,000 of principal payments on the debt. As of September 30, 2012, the remaining outstanding principal balance of the debt was approximately $6.4 million.

9. 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. Under the terms of the agreement, Montaur committed to extend up to $15 million in debt, which is available immediately, to the Company at a prime-based interest rate currently at approximately 10% per annum. Montaur has committed an additional $20 million upon FDA approval of Lymphoseek on consistent terms, with another $15 million potentially available on terms to be negotiated. No conversion features or warrants are associated with the facility. As of September 30, 2012, we have not drawn on the credit facility.

10. Derivative Instruments

Certain warrants to purchase our common stock are considered derivative liabilities under current accounting standards. At September 30, 2012, Navidea's Series GG warrants are considered derivative liabilities under these standards. We do not use derivative instruments for hedging of market risks or for trading or speculative purposes.

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. During the first nine months of 2011, certain outside investors exercised 1,578,948 Series CC warrants, 1,578,948 Series DD warrants, 810,000 Series V warrants, and 60,000 Series Z warrants, resulting in reclassification of $1.4 million 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, 2012 and 2011 resulted in net decreases in the estimated fair values of the derivative liabilities of approximately $284,000 and $7,000, respectively, which were recorded as non-cash income. The net effect of marking the Company's derivative liabilities to market during the nine-month periods ended September 30, 2012 and 2011 resulted in net (decreases) increases in the estimated fair values of the derivative liabilities of approximately ($7,000) and $957,000, respectively, which were recorded as non-cash (income) expense. The total estimated fair value of the remaining derivative liabilities was $510,000 and $569,000 as of September 30, 2012 and December 31, 2011, respectively.

11. Sublicense Agreement

On July 31, 2012, we entered into an agreement with Alseres Pharmaceuticals, Inc. (Alseres) to sublicense E-IACFT Injection (NAV5001), an Iodine-123 radiolabeled imaging agent being developed as an aid in the diagnosis of Parkinson's disease and other movement disorders, with a potential use as a diagnostic aid in dementia. Under the terms of the sublicense agreement, Alseres granted Navidea an exclusive, worldwide sublicense to research, develop and commercialize NAV5001. The final terms of the agreement required Navidea to make a one-time sublicense

execution payment to Alseres equal to (i) $175,000 in cash and (ii) 300,000 shares of our common stock.

The sublicense agreement also provides for contingent milestone payments of up to $2.9 million, $2.5 million of which will principally occur at the time of product registration or upon commercial sales, and the issuance of up to an additional 1.15 million shares of Navidea common stock, 950,000 shares of which are issuable at the time of product registration or upon commercial sales. In addition, the sublicense terms anticipate royalties on annual net sales of the approved product which are consistent with industry-standard terms and certain sublicense extension fees, payable in cash and shares of common stock, in the event certain diligence milestones are not met.

12. Stock Warrants

During the first nine months of 2012, an outside investor exercised 20,000 Series V warrants in exchange for issuance of 20,000 shares of our common stock, resulting in gross proceeds of $6,200.

At September 30, 2012, there are 17.5 million warrants outstanding to purchase our common stock. The warrants are exercisable at prices ranging from $0.32 to $2.375 per share with a weighted average exercise price of $0.56 per share.

13. Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases, and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. Due to the uncertainty surrounding the realization of the deferred tax assets in future tax returns, all of the deferred tax assets have been fully offset by a valuation allowance at September 30, 2012 and December 31, 2011. An estimated provision for income taxes related to income from discontinued operations was offset by the estimated tax benefit related to the loss from continuing operations during the three-month and nine-month periods ended September 30, 2011.

14. Supplemental Disclosure for Statements of Cash Flows

During the nine-month periods ended September 30, 2012 and 2011, we paid interest aggregating $476,000 and $3,000, respectively. During the nine-month periods ended September 30, 2012 and 2011, we issued 17,390 and 35,233 shares of our common stock, respectively, as matching contributions to our 401(k) plan. During the nine-month period ended September 30, 2012, we issued 300,000 shares of our common stock as partial payment for the execution of a sublicense agreement. See Note 11.

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 and Section 21E of the Exchange Act. 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 and radiopharmaceutical agents. We are currently developing four radiopharmaceutical agent platforms. The first, Lymphoseek® (technetium Tc 99m tilmanocept) Injection, is a novel, receptor-targeted, small-molecule, investigational radiopharmaceutical used in lymphatic mapping procedures that are performed to help stage 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. The second, NAV4694, is an 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). The third, E-IACFT (NAV5001), is an Iodine-123 radiolabeled single photon emission computed tomography (SPECT) imaging agent being developed as an aid in the diagnosis of Parkinson's disease and other movement disorders, with potential use as a diagnostic aid in dementia. The fourth, 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. All of these drug products 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 make progress in executing 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 Lymphoseek product candidate. We expect our overall research and development expenditures to continue to be significantly higher during 2012 as compared to 2011 due to the expansion of our clinical, regulatory, and business development staff and efforts that support the commercialization of Lymphoseek, further development of NAV4694, NAV5001 and RIGScan, and the potential sourcing and development of additional pipeline product candidates. The level to which the expenditures rise will depend on the extent to which we are able to execute on these strategic initiatives.

Lymphoseek

The initial pre-clinical evaluations of Lymphoseek were completed by the University of California, San Diego (UCSD) in 2001. Since that time, Navidea, in cooperation with UCSD, has completed or initiated five Phase 1 clinical trials, one multi-center Phase 2 trial and three multi-center Phase 3 trials involving Lymphoseek. Two comprehensive Phase 3 studies were completed in subjects with breast cancer and melanoma. These pivotal Phase 3 results have been presented at scientific conferences of a number of the world's leading oncology associations and nuclear medicine societies, including the American Society of Clinical Oncology and the Society for Nuclear Medicine. Earlier-phase studies conducted at UCSD through grants from the Susan G. Komen Breast Cancer Research Foundation have been published in leading medical journals including Journal of Nuclear Medicine and Annals of Surgical Oncology.

In June 2012, we published data developed from Phase 3 trials of Lymphoseek demonstrating important performance characteristics of Lymphoseek compared to a commercially available radiolabeled colloid used in intra-operative lymphatic mapping. The analysis evaluated the performance of Lymphoseek to a meta-analysis of published data for 99m-Tc-labeled nanocolloid human serum albumin (Nanocoll®), commercially available and considered the standard of care in Europe. The difference between Lymphoseek and Nanocoll in the parameters analyzed was statistically significant ($p < 0.0001$). The study, *"The efficacy of Tilmanocept in sentinel lymph node mapping and identification in breast cancer patients: a comparative review and meta-analysis of the 99m-Tc-labeled nanocolloid human serum albumin standard of care,"* can be found in the current online edition of the peer-reviewed journal *Clinical and Experimental Metastasis* [DOI 10.1007/s10585-012-9497-x]. Data for Nanocoll were derived from a meta-analysis of published literature that reported on the outcomes of localization rate (the proportion of patients with at least one localized lymph node), and degree of localization (the average number of localized nodes relative to the patient population). Data for Lymphoseek were derived from a meta-analysis of two completed Lymphoseek Phase 3 clinical trials. Lymphoseek demonstrated a localization rate of 99.9% whereas Nanocoll showed a 95.9% localization rate. The degree of Lymphoseek localization was 2.16 (CI 1.99-2.36), whereas the colloid standard of care showed 1.67 (CI 0.94-0.98). The difference between Lymphoseek and Nanocoll in both of these parameters was statistically significant ($p < 0.0001$). In September 2012, we announced the presentation of related data at the European Society of Surgical Oncology annual meeting.

In October 2012, we announced peer-reviewed publication of results of Lymphoseek from Phase 3 Clinical Trials in Melanoma in the Annals of Surgical Oncology. In the trials, a total of 154 patients with melanoma from 15 centers received Lymphoseek followed by vital blue dye (VBD) and then underwent sentinel lymph node mapping. Lymph nodes that demonstrated Lymphoseek uptake and/or the presence of blue dye were removed and examined for the presence of tumor. Of the 235 blue-dyed lymph nodes removed from the 154 patients, 232 (98.7%) demonstrated Lymphoseek uptake ($p<0.001$). The performance of Lymphoseek in intraoperative lymph node identification was also assessed. Of the 154 patients injected with both Lymphoseek and VBD who underwent surgical removal of the lymph nodes, 150 patients (97.4%) had at least one radioactive node due to Lymphoseek uptake, and 138 patients (89.6%) had at least one blue node. This difference was statistically significant ($p<0.002$). Melanoma-containing lymph nodes were detected in 34 (22.1%) patients; Lymphoseek identified all 45 melanoma-positive lymph nodes found in the 34 patients. Four of these 34 node-positive patients were detected exclusively by Lymphoseek. Blue dye detected 36 of the 45 melanoma-positive lymph nodes, but no melanoma-positive lymph nodes were detected exclusively by blue dye.

Clinical research continues with an ongoing third Phase 3 trial involving subjects with head and neck squamous cell carcinoma (NEO3-06). The NEO3-06 clinical study was designed to provide evidence of Lymphoseek performance in a third cancer type and to potentially expand the product label for Lymphoseek. While we are unable to predict the timing, this trial may reach a patient accrual point that would enable an interim analysis of the trial data in 2013.

Navidea submitted a new drug application (NDA) for Lymphoseek in August 2011, and was notified of acceptance of the NDA by the U.S. Food and Drug Administration (FDA) in October 2011. Following FDA's acceptance of our Lymphoseek NDA filing, FDA established a Prescription Drug User Fee Act (PDUFA) date for Lymphoseek of June 10, 2012. In April 2012, FDA notified us that the Agency had elected to modify the PDUFA date for Lymphoseek by 90 days to September 10, 2012 from the initial PDUFA date of June 10, 2012. On September 10, 2012, we received a Complete Response Letter (CRL) from FDA, denying our initial application for approval of Lymphoseek. We believe the decision was focused on deficiencies in current Good Manufacturing Practices (cGMP) identified by FDA during their pre-approval site inspections of third-party contract manufacturing facilities, and was not related to the efficacy or safety data filed within the Lymphoseek NDA. We have been working diligently with our advisors, contract manufacturers and FDA to address the third party cGMP manufacturing deficiencies noted in FDA's September CRL. On October 30, 2012, we resubmitted our NDA in response to the CRL. While we are unable to predict the timing for FDA review, we believe that the focused scope of the CRL and the corresponding information provided in the Company's response will facilitate a timely evaluation of the resubmission. We continue to believe the review process will not entail a full re-evaluation of the NDA and that the information we have provided will support an expeditious review. Our focus continues to be Lymphoseek approval and launch in the U.S. However, given the nature of the FDA review process, we cannot assure you that we will not experience further delays.

In February 2012, Navidea was also advised by the European Medicines Agency (EMA) Committee for Medicinal Products for Human Use that the Committee has adopted the advice of the Scientific Advice Working Party (SAWP) regarding the Lymphoseek development program and has determined that Lymphoseek is eligible for a Marketing Authorisation Application (MAA) submission based on clinical data accumulated from clinical studies completed to date and supporting clinical literature. While we intend to submit our MAA to the EMA by the end of 2012, our focus on the U.S. NDA for Lymphoseek may cause us to delay the submission of the MAA until early 2013.

NAV4694

NAV4694 is a 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. It binds to beta-amyloid deposits in the brain that can then be imaged in PET scans. Amyloid plaque pathology is a required feature of AD and the presence of amyloid pathology is a supportive feature for diagnosis of probable AD. Patients who are negative for amyloid pathology do not have AD.

Based on the data accumulated to date, NAV4694 appears to have better sensitivity and specificity in detecting beta-amyloid than other agents in development. 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. The uptake in background tissue, referred to as white matter, is low. Greater contrast may enable the ability to detect smaller amounts of amyloid and earlier identification of disease, as well as the opportunity to detect smaller changes in amyloid levels and monitor disease progression over time.

NAV4694 has been studied in rigorous pre-clinical studies and several clinical trials in humans. Clinical studies through Phase 2a have included more than 80 patients to date, both suspected AD patients and healthy volunteers. No significant adverse events have been observed. Results suggest that NAV4694 has the potential ability to image patients quickly and safely with high sensitivity and specificity.

We are currently supporting ongoing Phase 2 clinical trials and advancing our development plans for NAV4694. In addition, we initiated a new Phase 2 trial in September 2012, primarily to expand the safety database for the compound. We also expect to initiate a Phase 3 trial in early 2013 to support registration in the U.S. and the EU.

NAV5001

In January 2012, we executed an option agreement with Alseres Pharmaceuticals, Inc. (Alseres) to sublicense NAV5001. Under the terms of the option agreement, Navidea paid Alseres an option fee of $500,000 for the exclusive right to negotiate a definitive sublicense agreement by June 30, 2012. In order to perform thorough due diligence, Navidea extended the option period from June 30, 2012, to July 31, 2012. On July 31, 2012, we entered into an agreement to sublicense NAV5001 from Alseres. Under the terms of the sublicense agreement, Alseres granted Navidea an exclusive, worldwide sublicense to research, develop and commercialize NAV5001. The final terms of the agreement required Navidea to make a one-time sublicense execution payment to Alseres equal to (i) $175,000 in cash and (ii) 300,000 shares of our common stock. The sublicense agreement also provides for contingent milestone payments of up to $2.9 million, $2.5 million of which will principally occur at the time of product registration or upon commercial sales, and the issuance of up to an additional 1.15 million shares of Navidea common stock, 950,000 shares of which are issuable at the time of product registration or upon commercial sales. In addition, the sublicense terms anticipate royalties on annual net sales of the approved product which are consistent with industry-standard terms and certain sublicense extension fees, payable in cash and shares of common stock, in the event certain diligence milestones are not met.

NAV5001 is a patented, novel, 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 Parkinson’s disease. 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 Parkinson’s disease.

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 Parkinson’s disease 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.

RIGScan

Radioimmunoguided surgery (RIGS®) is a technique to provide diagnostic information during cancer surgery. RIGS is intended to enable a surgeon to identify and delineate occult or metastatic cancerous tissue “targeted” through the use of a radiolabeled, cancer-specific targeting antibody. The antibody is administered prior to surgery and is identified by pre-operative imaging or during surgery with a gamma detection device/probe, thereby assisting a surgeon in identifying the location of cancerous tissues. Before surgery, a cancer patient is injected with the antibody which circulates throughout the patient’s body and binds specifically to cancer cell antigens or receptors. Concentrations of the antibody within affected tissue are then detected using imaging methods prior to surgery or a gamma probe during surgery to direct the surgeon to targeted tissue for removal.

Our RIGScan technology is a radiolabeled murine monoclonal antibody that serves as the biologic targeting agent for intraoperative detection of occult or metastatic cancer. The antibody localizes or binds to tumor antigen called TAG-72 expressed on solid tumor cancers. RIGScan is intended to be used in conjunction with other diagnostic methods for the detection of the extent and location of occult tumor and tumor metastases in patients with such cancers, potentially including colorectal cancer, ovarian cancer, prostate 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 RIGScan approach 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 Disease of the Colon and Rectum. In 1996, Navidea submitted applications to EMA and 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, but 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 EMA in November 1997.

To resume RIGScan development, we filed a new investigational new drug (IND) request with FDA in late 2010. We held a pre-IND meeting with FDA in February 2011 to define the basic chemistry, manufacturing and control (CMC) requirements needed to resume clinical development efforts on RIGScan. FDA provided guidance regarding enhancing our manufacturing platform, including process improvements to increase manufacturing efficiency and the quality of the underlying biologic antibody and potentially transitioning from a murine-based antibody to a human-based antibody. In August 2011, we also held a meeting with the SAWP of the EMA and received similar guidance. With this collective guidance, we have transitioned from a murine antibody to a humanized antibody. We were recently awarded a grant from the National Institutes of Health to further the development of 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 investigational 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 the start of clinical development; however, as the scope and required resources for the RIGScan program, particularly in light of other development opportunities such as Lymphoseek, NAV4694, NAV5001, or other agents continues to be assessed, the timing and scope of our plans for RIGScan may be affected.

RIGScan is a biologic drug that has not been produced for several years. We have completed the initial steps in re-characterizing the antibody cell line and are in the process of evaluating the use of our current humanized antibody in future clinical testing. During the third quarter of 2009, we had announced that we executed a Biopharmaceutical Development and Supply Agreement with Laureate Biopharmaceutical Services, Inc. (Laureate Biopharma). This agreement supports manufacturing process development work, evaluation of the viability of the cell line and its productivity, and the initial steps in re-validating the clinical grade and commercial production process for the humanized version of the RIGScan antibody. Laureate Biopharma has made progress in the re-validation of the manufacturing process and has completed certain initial biologic characterization activities. Our development plans for RIGScan also include the consideration of alternative radiolabeling processes. We will need to establish robust manufacturing and radiolabeling capabilities for the antibody in order to meet the regulatory needs for the RIGScan product.

Outlook

We spent approximately $12.5 million and $8.2 million on research and development activities during the nine-month periods ended September 30, 2012 and 2011, respectively. Of the total amounts we spent on research and development during those periods, excluding costs related to our internal research and development headcount and our general and administrative staff which we do not currently allocate among the various development programs that we have underway, we incurred charges by program as follows:

	Nine Months Ended September 30,	
Development Program	2012	2011
Lymphoseek	$4,243,933	$4,587,488
NAV4694	2,177,007	—
NAV5001	2,083,699(a)	—
RIGScan	254,721	1,069,906

(a) Amount includes approximately $1.8 million in option and sublicense fees paid in 2012.

Due to the advancement of our efforts with Lymphoseek, NAV4694, NAV5001, RIGScan, and potentially other programs, we expect our drug-related development and commercialization expenses for 2012 to continue to exceed 2011.

With respect to Lymphoseek, until the NDA review is complete, we will continue to support the NDA to the fullest extent possible and to prepare for commercial launch in the U.S. with our marketing partner, Cardinal Health.

During the remainder of 2012, we expect to incur additional development expenses related to supporting the NDA review of Lymphoseek, our preparation for filing an MAA in the EU, our NEO3-06 clinical trial and potentially studies to support Lymphoseek in a post-commercialization setting and support the other product activities related to the potential marketing registration of Lymphoseek in the U.S. and other markets. In addition, we expect to incur significant costs during the remainder of 2012 to support our business development and commercialization activities surrounding Lymphoseek. We cannot assure you that Lymphoseek will achieve regulatory approval in the U.S., the EU or any market, or if approved, that it will achieve market acceptance.

We also expect to incur significant expenses for NAV4694 during the remainder of 2012 related to ongoing additional Phase 2 clinical trials and preparing for the initiation of a pivotal Phase 3 clinical trial in 2013, as well as costs for manufacturing-related activities required prior to filing for regulatory clearance to market. NAV4694 is currently not expected to contribute revenue to the Company until 2016 at the earliest. We cannot assure you that further clinical trials for this product will be successful, that the agent will ultimately achieve regulatory approval, or if approved, the

extent to which it will achieve market acceptance.

We are in the process of finalizing a regulatory approach and draft of the clinical development plan for NAV5001 by the end of 2012. The timing and extent of expected expenditures related to NAV5001 will be better known following the completion of such plan.

We are in the process of evaluating the business, manufacturing, development and regulatory pathways forward with respect to RIGScan. 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 FDA or EMA will clear RIGScan for marketing, or that it will be successfully introduced or 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.

Discontinued Operations

From our inception through August 2011, we developed and marketed a line of medical devices, the neoprobe® GDS gamma detection systems (the GDS Business). However, following an analysis of our strategic goals and objectives, our Board of Directors authorized, and our stockholders approved, the sale of the GDS Business as well as the disposal of the related extended warranty contracts to Devicor Medical Products, Inc. for a net purchase price of $30.3 million.

In 2009, the Company's Board of Directors decided to discontinue the operations of, and attempt to sell, our Cardiosonix subsidiary. This decision was based on the determination that the blood flow measurement device segment was no longer considered a strategic initiative of the Company, due in large part to positive achievements related to our other device product and drug development initiatives. The operations of Cardiosonix were effectively wound down during 2011.

Our consolidated balance sheets and statements of operations have been reclassified to reflect the GDS Business and Cardiosonix as discontinued operations, as required. Cash flows associated with the operation of the GDS Business and Cardiosonix have been combined within operating, investing and financing cash flows, as appropriate, in our consolidated statements of cash flows.

Results of Operations

This discussion of our Results of Operations focuses on describing results of our operations as if we had not operated the discontinued operations discussed above during the periods being disclosed. In addition, since our radiopharmaceuticals are not yet generating commercial revenue, the discussion of our revenue focuses on the grant and other revenue we have received and our operating variances focus on our radiopharmaceutical development programs and the supporting general and administrative expenses.

We recognized Ohio Third Frontier grant revenue of approximately $950,000 through 2011, and expect to recognize the remaining $50,000 as revenue in the next 12 months. During the nine-month period ended September 30, 2012, Navidea recognized an additional $12,000 of miscellaneous grant revenue. Also during the nine-month period ended

September 30, 2012, Navidea recognized revenue of $60,000 related to reimbursement of certain Lymphoseek commercialization activities, for which the Company had principal responsibility, by our distribution partner, Cardinal Health, Inc.

Three Months Ended September 30, 2012 and 2011

Revenue. We did not recognize any revenue during the third quarter of 2012. Revenue of $256,000 during the third quarter of 2011 was related to the Ohio Third Frontier grant to support Lymphoseek development.

Research and Development Expenses. Research and development expenses increased $2.2 million, or 59%, to $6.1 million during the third quarter of 2012 from $3.9 million during the same period in 2011. The increase was primarily due to net increases in drug project expenses related to (i) increased NAV4694 development costs of $1.8 million, including imaging core lab, technology transfer, clinical activities, PET production, manufacturing-related costs, and consulting fees, and (ii) increased NAV5001 development costs of $1.4 million, including sublicense fees of $1.3 million coupled with due diligence and consulting costs; offset by (iii) a net decrease in Lymphoseek development costs of $817,000 resulting from the $1.5 million FDA filing fee and UCSD license milestone payment related to filing the Lymphoseek NDA during the third quarter of 2011 coupled with decreased clinical activities, offset by increased manufacturing-related and regulatory consulting costs related to preparation for filing a MAA with EMA, and (iv) a net decrease in RIGScan development costs of $471,000, primarily related to manufacturing. The net increase in research and development expenses also included an increase in headcount and related expenses required for expanded development efforts of $185,000, as well as increased costs related to pharmacovigilance activities, travel and professional services.

Selling, General and Administrative Expenses. Selling, general and administrative expenses remained steady at $2.9 million during the third quarter of 2012 and 2011. Increased marketing costs related to the pending commercial launch of Lymphoseek of $597,000 and increased compensation costs related to increased headcount and incentive-based compensation of $168,000 were offset by decreased stock compensation related to the separation of our former President and CEO of $817,000.

Other Income (Expense). Other expense, net, was $29,000 during the third quarter of 2012 as compared to other income, net, of $13,000 during the same period in 2011. Interest expense increased $314,000 to $315,000 during the third quarter of 2012 due to the note payable we entered into in December 2011. Of the interest expense in the third quarter of 2012, $147,000 was non-cash in nature related to the amortization of debt issuance costs and debt discounts resulting from the warrants issued and conversion features embedded in the note. During the third quarter of 2012 and 2011, we recorded income of $284,000 and $7,000, respectively, related to the decreases in derivative liabilities resulting from the requirement to mark our derivative liabilities to market.

Income Taxes. An estimated tax provision of $5.7 million related to the gain on the sale of discontinued operations and $1.0 million related to income from discontinued operations was offset by an estimated tax benefit of $6.4 million related to the loss from continuing operations during the third quarter of 2011.

Gain on Sale of Discontinued Operations. Gain on sale of discontinued operations related to the sale of our GDS Business to Devicor was $20.1 million during the third quarter of 2011. The sales price of $30.3 million included a cash payment of $30.0 million and an accrued net working capital adjustment of an additional $254,000. The proceeds were offset by $2.2 million in legal and other fees related to the sale, $2.3 million in net balance sheet dispositions and write-offs, and $5.7 million of estimated taxes, as noted above.

Income from Discontinued Operations. The loss from discontinued operations was $221,000, net of $1.0 million in estimated taxes, during the third quarter of 2011 and was primarily related to the operation of our GDS Business, which was sold to Devicor in August 2011.

Nine Months Ended September 30, 2012 and 2011

Revenue. Revenue of $60,000 during the first nine months of 2012 was related to reimbursement of certain Lymphoseek commercialization activities by our distribution partner, Cardinal Health, Inc. Revenue of $592,000 during the first nine months of 2011 was related to the Ohio Third Frontier grant to support Lymphoseek development. Additional revenue of $12,000 and $6,000 during the first nine months of 2012 and 2011, respectively, was related to Ohio Third Frontier grants to support student internships.

Research and Development Expenses. Research and development expenses increased $4.4 million, or 54%, to $12.5 million during the first nine months of 2012 from $8.2 million during the same period in 2011. The increase was primarily due to net increases in drug project expenses related primarily to (i) increased NAV4694 development costs of $2.2 million, including imaging core lab, technology transfer, consulting fees, clinical activities, PET production, manufacturing-related costs, and project management fees, and (ii) increased NAV5001 development costs of $2.1 million, including option and sublicense fees of $1.8 million coupled with due diligence and consulting costs, and (iii) consulting costs related to potential pipeline products of $203,000; offset by (iv) a net decrease in Lymphoseek development costs of $344,000 resulting from the $1.5 million FDA filing fee and UCSD license milestone payment related to filing the Lymphoseek NDA during the first nine months of 2011 coupled with decreased clinical activities, offset by increased manufacturing-related costs, consulting costs related to preparation for a potential FDA Advisory Committee meeting, and regulatory consulting costs related to preparation for filing a MAA with EMA, and (v) a net decrease in RIGScan development costs of $815,000, primarily related to manufacturing. The net increase in research and development expenses also included an increase in headcount and related expenses required for expanded development efforts of $546,000, as well as increased costs related to pharmacovigilance activities, travel, recruiting, training, general office expenses and other expenses of $461,000.

Selling, General and Administrative Expenses. Selling, general and administrative expenses increased $988,000, or 13%, to $8.5 million during the first nine months of 2012 from $7.5 million during the same period in 2011. The net increase was primarily due to our formation of a marketing and business development team during the second half of 2011 to prepare for the commercial launch of Lymphoseek. Increased marketing costs related to the pending commercial launch of Lymphoseek of $2.1 million, increased compensation costs of $1.2 million related to increased headcount and incentive-based compensation, and increased travel, insurance, recruiting and general office expenses to support the increased headcount of $421,000 were offset by a decrease in separation costs of $2.7 million related to our former President and CEO which were recorded during the first nine months of 2011.

Other Income (Expense). Other expense, net, was $960,000 during the first nine months of 2012 as compared to $948,000 during the same period in 2011. Interest expense increased $927,000 to $930,000 during the first nine months of 2012 from $3,000 for the same period in 2011, due to the note payable we entered into in December 2011. Of the interest expense in the first nine months of 2012, $407,000 was non-cash in nature related to the amortization of debt issuance costs and debt discounts resulting from the warrants issued and conversion features embedded in the note. During the first nine months of 2012 and 2011, we recorded income of $7,000 and charges of $957,000, respectively, related to the changes in derivative liabilities resulting from the requirement to mark our derivative liabilities to market.

Income Taxes. An estimated tax provision of $5.7 million related to the gain on the sale of discontinued operations and $1.0 million related to income from discontinued operations was offset by an estimated tax benefit of $6.4 million related to the loss from continuing operations during the first nine months of 2011.

Gain on Sale of Discontinued Operations. Gain on sale of discontinued operations related to the sale of our GDS Business to Devicor was $19.5 million during the first nine months of 2011. The sales price of $30.3 million included a cash payment of $30.0 million and an accrued net working capital adjustment of an additional $254,000. The proceeds were offset by $2.8 million in legal and other fees related to the sale, $2.3 million in net balance sheet dispositions and write-offs, and $5.7 million of estimated taxes, as noted above.

Income from Discontinued Operations. The income from discontinued operations was $3.3 million, net of $1.0 million in estimated taxes, during the first nine months of 2011 and was primarily related to the operation of our GDS Business, which was sold to Devicor in August 2011.

Liquidity and Capital Resources

Cash balances decreased to $11.2 million at September 30, 2012 from $28.6 million at December 31, 2011. The net decrease was primarily due to cash used to fund our operations, mainly for research and development activities.

Operating Activities. Cash used in operations increased $10.3 million to $16.6 million during the first nine months of 2012 compared to $6.3 million during the same period in 2011.

Inventory levels decreased to $641,000 at September 30, 2012 from $822,000 at December 31, 2011. Pharmaceutical work-in-process decreased related to reserving or writing off previously capitalized Lymphoseek inventory due to changes in our projections of the probability of future commercial use, and due to the consumption of Lymphoseek inventory for previously unanticipated product development activities. Offsetting these decreases was an increase in pharmaceutical materials related to the completion of a new batch of the Lymphoseek drug substance. We expect inventory levels to remain steady for the remainder of 2012 as we do not anticipate producing additional drug inventory until 2013.

Accounts payable increased to $2.0 million at September 30, 2012 from $682,000 at December 31, 2011 primarily due to fluctuations in timing of receipt and payment of invoices. Accrued liabilities and other remained steady at $2.1 million at September 30, 2012 and December 31, 2011. Our payable and accrual balances will continue to fluctuate but will likely increase overall as we increase our level of development activity related to NAV4694, NAV5001 and other programs.

Investing Activities. Cash used in investing activities was $624,000 during the first nine months of 2012 compared to $27.1 million of cash provided during the same period in 2011. The sale of the GDS Business to Devicor in August 2011 provided $27.2 million, net of related expenses. Capital expenditures of $618,000 during the first nine months of 2012 were primarily for drug production equipment, software, computers, and furniture and fixtures for the new branch office in Andover, MA. Capital expenditures of $95,000 during the first nine months of 2011 were primarily for computers, software, and drug production equipment. We expect our overall capital expenditures for 2012 will be higher than in 2011. Payments for patent and trademark costs were $6,000 and $53,000 during the first nine months of 2012 and 2011, respectively.

Financing Activities. Cash used in financing activities was $204,000 during the first nine months of 2012 compared to $4.5 million of cash provided during the same period in 2011. The $204,000 provided by financing activities in the first nine months of 2012 consisted primarily of principal payments on the note payable we entered into in December 2011 of $620,000, payments of debt issuance costs of $154,000, payment for common stock repurchased from executives of $101,000, payment of preferred stock dividends of $75,000, payment of tax withholdings related to stock-based compensation of $9,000, and payments of capital leases of $4,000, offset by net proceeds from the issuance of common stock of $759,000. The $4.5 million provided by financing activities in the first nine months of 2011 consisted primarily of proceeds from the issuance of common stock of $7.1 million, offset by payments of tax withholdings related to stock-based compensation of $2.4 million, including costs related to the net exercise of stock options by our former President and CEO of $2.1 million, and principal payments on notes payable of $62,000, preferred stock dividends of $75,000, and capital leases of $7,000.

In December 2011, we executed a Loan and Security Agreement (the Loan Agreement) with Hercules Technology II, L.P. (Hercules), providing for a maximum borrowing of $10 million by the Company in two advances. Pursuant to the Loan Agreement, we issued Hercules: (1) a Secured Term Promissory Note in the principal amount of $7,000,000 (the First Advance), 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% (effective interest rate at September 30, 2012 and December 31, 2011 was 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). Additionally, the terms of the Loan Agreement provided Navidea with the option to draw a second advance in the principal amount of $3,000,000 if certain conditions were met by June 30, 2012. Such conditions were not met and Hercules no longer has an obligation to provide the additional $3,000,000. The Loan Agreement provided for an interest-only period beginning on December 29, 2011 and expiring on July 1, 2012. 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. As such, a portion of the principal, net of related discounts, has been classified as a current liability as of September 30, 2012. The outstanding balance of the debt is due December 1, 2014. Navidea has the option to pay up to $1.5 million of the principal amount of the debt in stock at a fixed conversion price of $2.77, subject to certain conditions. In addition, Hercules has the option to elect payment for up to

another $1.5 million of the principal amount of the debt by conversion at a fixed conversion price of $2.77.

In July 2012 and May 2011, Platinum-Montaur Life Sciences, LLC (Montaur) converted 3,063 and 917 shares, respectively, of their Series B Convertible Preferred Stock (the Series B) into 10,016,010 and 2,998,590 shares, respectively, of our common stock under the terms of the Series B. As of September 30, 2012, there were 6,020 shares of Series B outstanding which are convertible into 19,685,400 shares of our common stock.

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 July 2012, we entered into an agreement with Montaur to provide us with a credit facility of up to $50 million. Under the terms of the agreement, Montaur committed to extend up to $15 million in debt, which is available immediately, to the Company at a prime-based interest rate currently at approximately 10% per annum. Montaur has committed an additional $20 million upon FDA approval of Lymphoseek on consistent terms, with another $15 million potentially available on terms to be negotiated. No conversion features or warrants are associated with the facility.

On September 10, 2012, we received a CRL from FDA, denying our application for approval of Lymphoseek. We believe the decision was focused on cGMP deficiencies identified by FDA during their site inspections of third-party contract manufacturing facilities, and was not related to any efficacy or safety data filed within the Lymphoseek NDA. Our most significant near-term development priority is to continue our regulatory and pre-commercialization activities related to Lymphoseek. We continue to expect Lymphoseek-related research and development expenditures to decline following our resubmission of the NDA for review by FDA; however, we expect marketing expenses related to Lymphoseek to increase in preparation for the commercial launch. We continue to assess timelines and development costs for development of NAV4694, NAV5001 and RIGScan. We are also actively evaluating a number of different product licensing and/or acquisition opportunities. Costs related to in-licensing, acquiring and developing other late-stage radiopharmaceutical candidates that we are evaluating, coupled with development costs related to our existing product candidates, may result in the use of a material portion of our available funds.

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 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 credit facility with Montaur and our access to capital markets through our shelf registration provides us with adequate financial resources to continue to fund our business plan through the point where we would start to generate positive cash flow following FDA approval and the commercialization of Lymphoseek. However, we cannot assure you that Lymphoseek will achieve FDA approval, or if approved, that it will generate our expected levels of sales and cash flow. If Lymphoseek is not approved, or its approval is further delayed, we will need to revise our financial, operating and development plans.

We will continue to evaluate our timelines and strategic needs, and although we have not decided whether, when or how much capital might be raised under the shelf registration statement or the credit facility, we will continue our efforts to maintain a strong balance sheet. Even if we decide to attempt to raise additional capital, we cannot assure you that 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.

Critical Accounting Policies

We consider the following accounting policies to be critical to our results of operations and financial condition.

Revenue Recognition. We currently generate revenue primarily 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.

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. Compensation cost arising from stock-based awards is recognized as expense using the straight-line method over the vesting period.

- *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. Uncertain timing of product approvals, variability in product launch strategies, 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.

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Item 3. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk. As of September 30, 2012, our $11.2 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.

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, 2012 and 2011, we recorded foreign currency transaction losses of $13,000 and $2,000, respectively.

Equity Price Risk. We do not use derivative instruments for hedging of market risks or for trading or speculative purposes. Derivative instruments embedded in contracts, to the extent not already a free-standing contract, are bifurcated and accounted for separately. All derivatives are recorded on the consolidated balance sheet at fair value in accordance with current accounting guidelines for such complex financial instruments. The fair value of warrant liabilities is determined using various inputs and assumptions, one of which is the price of Company stock. As of September 30, 2012, we had approximately $510,000 of derivative liabilities recorded on our balance sheet related to 333,333 Series GG warrants. A hypothetical 50% increase in our stock price would increase the value of our derivative liabilities by approximately $390,000. A hypothetical 50% decrease in our stock price would decrease the value of our derivative liabilities by approximately $336,000.

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, 2012. 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 systems 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, 2012, 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

There have been the following material changes 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, 2011, filed with the SEC on March 7, 2012:

We cannot guarantee that we will obtain regulatory approval to manufacture or market any of our drug candidates and our approval to market our products may be delayed as a result of the regulatory review process.

Obtaining regulatory approval to market drugs to diagnose or treat cancer is expensive, difficult and risky. Preclinical and clinical data as well as information related to the chemistry, manufacturing and control (CMC) processes of drug production can be interpreted in different ways which could delay, limit or preclude regulatory approval. Negative or inconclusive results, adverse medical events during a clinical trial, or issues related to CMC processes could delay, limit or prevent regulatory approval.

Our near-term financial success depends in large part on obtaining regulatory approval to market Lymphoseek in the U.S. The NDA for Lymphoseek, intended for use in intraoperative lymphatic mapping across a broad range of cancers, was originally submitted to the U.S. Food and Drug Administration (FDA) for review in August 2011.

Following FDA's acceptance of our Lymphoseek NDA filing, FDA established a Prescription Drug User Fee Act (PDUFA) date for Lymphoseek of June 10, 2012. In April 2012, we were notified by FDA that our PDUFA date had been modified to September 10, 2012, a 90-day extension. As a part of the review, FDA evaluated the pre-clinical, clinical and CMC data supporting our application, and, as is also typical of such reviews, conducted site audits of our facilities and those of the clinical sites where the referenced clinical trials were performed, as well as of contract manufacturing facilities and third party vendors being used in the manufacturing and quality assessment processes for Lymphoseek. On September 10, 2012, we received a Complete Response Letter (CRL) from FDA, denying our application for approval of Lymphoseek. We believe the decision was focused on deficiencies in current Good Manufacturing Practices (cGMPs) identified by FDA during their site inspections of third-party contract manufacturing facilities, and was not related to any efficacy or safety data filed within the Lymphoseek NDA. We have been working diligently with our advisors, contract manufacturers and FDA to address the deficiencies in third party cGMPs noted in FDA's September CRL. On October 30, 2012, we resubmitted our NDA in response to the CRL. While we are unable to predict the timing for FDA review, we believe that the focused scope of the CRL and the corresponding information provided in the Company's responses will facilitate a timely evaluation of the resubmission. We continue to believe the review process will not entail a full re-evaluation of the NDA and that the information we have provided will support an expeditious review.

Further review of the resubmission to the NDA, or other inquiries by FDA, could raise additional questions or issues, requiring us to prepare responses or submit additional data that could further delay approval of the NDA. Further delays in the approval of the NDA could result in additional delays in our expected revenue from Lymphoseek and increase the use of our cash until any deficiencies cited by FDA are corrected and another resubmission to the NDA is submitted and reviewed by FDA. Such potential consequences may negatively affect our business, financial condition and results of operations in a material way. We cannot assure you that Lymphoseek will achieve regulatory approval and commercial launch.

If we do not successfully develop our product candidates into marketable products, we may be unable to generate significant revenue or become profitable.

We divested our primary commercial product line, the neoprobe GDS line of gamma detection medical devices, in August 2011. Currently, we do not have any revenue generating products, and unless we are able to develop one of our product candidates, such as Lymphoseek, into an approved commercial product, we will not generate any significant revenues from product sales, milestone payments or otherwise. As discussed previously, we received a CRL regarding the Lymphoseek NDA and resubmitted it for review by FDA on October 30, 2012. NAV4694, NAV5001 and RIGScan are in various stages of clinical development. Regulatory approval for Lymphoseek and/or additional clinical trials for NAV4694, NAV5001, RIGScan or other product candidates may not be successful and, even if they are, we may not be successful in developing any of them into a commercial product. In addition, many companies in the pharmaceutical industry suffer significant setbacks in advanced clinical trials even after reporting promising results in earlier trials. Even if our trials are viewed as successful, we may not get regulatory approval. Our product candidates will be successful only if:

- they are developed to a stage that will enable us to commercialize them or sell related marketing rights to pharmaceutical companies;
- we are able to commercialize them in clinical development or sell the marketing rights to third parties; and
- upon being developed, they are approved by the regulatory authorities.

We are dependent on the achievement of these goals in order to generate revenues. The failure to generate such revenues may preclude us from continuing our research and development of these and other product candidates.

If we are not successful in licensing or acquiring additional drug candidates or technologies to expand our product pipeline, our future product portfolio and potential profitability could be harmed.

One component of our business strategy is to in-license drug compounds developed by other pharmaceutical and biotechnology companies or academic research laboratories. All of our product candidates in clinical development are in-licensed from third parties, including Lymphoseek, NAV4694, NAV5001 and RIGScan. We may not successfully acquire additional drug candidates or technologies to expand our product pipeline. The number of such candidates and technologies is limited. Competition among large pharmaceutical companies and biopharmaceutical companies for promising drug candidates and technologies is intense because such companies generally desire to expand their product pipelines through purchase or in-licensing. If we fail to expand our product pipeline, our potential future revenues may be adversely affected.

Clinical trials for our radiopharmaceutical product candidates will be lengthy and expensive and their outcome is uncertain.

Before obtaining regulatory approval for the commercial sale of any product candidates, we must demonstrate through preclinical testing and clinical trials that our product candidates are safe and effective for use in humans. Conducting clinical trials is a time consuming, expensive and uncertain process and may take years to complete. During 2011, we successfully completed a second Phase 3 clinical trial in subjects with breast cancer or melanoma for our most advanced radiopharmaceutical product candidate, Lymphoseek. In addition, we are currently enrolling subjects in a third Phase 3 clinical trial in subjects with head and neck squamous cell carcinoma.

With respect to NAV4694, AstraZeneca has completed clinical development through a Phase 2a level. We recently commenced our clinical development through some additional Phase 2 testing, mainly intended to expand the safety population, and we intend to commence Phase 3 testing of NAV4694 in 2013, but these plans could also experience complications and delays.

With respect to NAV5001, Alseres Pharmaceuticals, Inc. (Alseres), the party from whom we have sublicensed NAV5001, had previously completed five clinical trials in over 600 subjects. Alseres received a Phase 3 Special Protocol Assessment (SPA) from FDA for NAV5001 in 2009. We have held preliminary discussions with FDA regarding the SPA and expect to update the SPA over the coming months.

In August 2011, we held a meeting regarding RIGScan with the Scientific Advice Working Party (SAWP) of the European Medicines Agency (EMA) and received similar guidance as we received from FDA, as well as the suggestion that we consider use of a humanized version of the RIGS antibody. With this collective guidance, we have changed our development plans from a murine-based antibody to a humanized antibody on our development and regulatory timelines. As the scope and required resources for other development opportunities such as for NAV4694 and/or NAV5001 continues to be assessed, the timing and scope of our development and commercialization plan for RIGScan may be affected.

Historically, the results from preclinical testing and early clinical trials often do not predict the results obtained in later clinical trials. Frequently, drugs that have shown promising results in preclinical or early clinical trials subsequently fail to establish sufficient safety and efficacy data necessary to obtain regulatory approval. At any time during the clinical trials, we, the participating institutions, FDA or EMA might delay or halt any clinical trials for our product candidates for various reasons, including:

- ineffectiveness of the product candidate;
- discovery of unacceptable toxicities or side effects;
- development of disease resistance or other physiological factors;
- delays in patient enrollment; or
- other reasons that are internal to the businesses of our potential collaborative partners, which reasons they may not share with us.

While we have achieved some level of success in our clinical trials for Lymphoseek, and our licensing partners have also achieved successful outcomes from earlier trials of NAV4694 and NAV5001, the results of these clinical trials, as well as pending and future trials for these and other product candidates that we may develop or acquire, are subject to review and interpretation by various regulatory bodies during the regulatory review process and may ultimately fail to demonstrate the safety or effectiveness of our product candidates to the extent necessary to obtain regulatory approval or that commercialization of our product candidates is worthwhile. Any failure or substantial delay in successfully completing clinical trials and obtaining regulatory approval for our product candidates could materially harm our business.

We may be unable to establish or contract for the pharmaceutical manufacturing capabilities necessary to develop and commercialize our potential products.

We are in the process of establishing commercial manufacturing capabilities on a third-party contract basis for our Lymphoseek product and clinical manufacturing capabilities for our other radiopharmaceutical compounds. We intend to rely on third-party contract manufacturers to produce sufficiently large quantities of drug materials that are and will be needed for clinical trials and commercialization of our potential products. Third-party manufacturers may not be able to meet our needs with respect to timing, quantity or quality of materials.

We have a supply agreement with Reliable Biopharmaceutical Corporation (Reliable) to manufacture the drug substance for our Lymphoseek product and we currently use OSO BioPharmaceuticals Manufacturing, LLC (OsoBio) for the finishing and vialing of our Lymphoseek product. However, if we are unable to contract for a sufficient supply of needed materials on acceptable terms, or if we should encounter delays or difficulties in our relationships with manufacturers, our clinical trials may be delayed, thereby delaying the submission of product candidates for regulatory approval and the market introduction and subsequent commercialization of our potential products. Any such delays may lower our revenues and potential profitability.

We and any third-party manufacturers that we may use must continually adhere to cGMPs and regulations enforced by FDA through its facilities inspection program and/or foreign regulatory authorities where our products will be tested and/or marketed. If our facilities or the facilities of third-party manufacturers cannot pass a pre-approval plant inspection, FDA and/or foreign regulatory authorities will not grant approval to market our product candidates. In complying with these regulations and foreign regulatory requirements, we and any of our third-party manufacturers will be obligated to expend time, money and effort on production, record-keeping and quality control to assure that our potential products meet applicable specifications and other requirements. The FDA and other regulatory authorities may take action against a contract manufacturer who violates cGMPs. We recently received a CRL in response to our NDA for Lymphoseek based on deficiencies identified during site inspections of some of our third party contract manufacturing facilities as a part of the NDA review process. We have been working with FDA and our contract manufacturers to clarify the identified deficiencies and believe the majority of the deficiencies have now been addressed. As a result, we resubmitted our NDA on October 30, 2012. However, we cannot assure you that the identified deficiencies have been addressed to FDA's satisfaction or to support the approval of the NDA. Should the Lymphoseek NDA be approved, failure to continually comply with FDA, EMA or other applicable regulations may cause us to curtail or stop the manufacture of such products until we regain regulatory compliance.

We may lose out to larger or better-established competitors.

The biotechnology industry is intensely competitive. Some of our competitors have significantly greater financial, technical, manufacturing, marketing and distribution resources as well as greater experience in the pharmaceutical industry than we have. The particular medical conditions our product lines address can also be addressed by other medical procedures or drugs. Many of these alternatives are widely accepted by physicians and have a long history of use. Physicians may use our competitors' products and/or our products may not be competitive with other technologies. For example, Eli Lilly recently announced that it had received approval to market florbetapir, a first-generation beta-amyloid imaging agent. We are also aware of two additional first-generation beta-amyloid imaging agents in late stages of development by large pharmaceutical companies. If our competitors are successful in establishing and maintaining market share for their products, our sales and revenues may not occur at the rate we anticipate. In addition, our current and potential competitors may establish cooperative relationships with larger companies to gain access to greater research and development or marketing resources. Competition may result in price reductions, reduced gross margins and loss of market share.

If any of our license agreements for intellectual property underlying Lymphoseek, NAV4694, NAV5001 or RIGScan, or any other products or potential products are terminated, we may lose the right to develop or market that product.

We have licensed intellectual property, including patents and patent applications relating to intellectual property for Lymphoseek, NAV4694, NAV5001 and RIGScan. We may also enter into other license agreements or acquire other product candidates. The potential success of our product development programs depend on our ability to maintain rights under these licenses, including our ability to achieve development or commercialization milestones contained in the licenses. Under certain circumstances, the licensors have the power to terminate its agreement with us if we fail to meet our obligations under these licenses. We may not be able to meet our obligations under these licenses. If we

default under any license agreement, we may lose our right to market and sell any products based on the licensed technology.

We and our collaborators, including AstraZeneca and Alseres, may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on all of our product candidates and products, when and if we have any, in every jurisdiction would be prohibitively expensive. Competitors may use our technologies in jurisdictions where we or our licensors have not obtained patent protection to develop their own products. These products may compete with our products, when and if we have any, and may not be covered by any of our or our licensors' patent claims or other intellectual property rights.

The laws of some non-U.S. countries do not protect intellectual property rights to the same extent as the laws of the United States, and many companies have encountered significant problems in protecting and defending such rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biotechnology and/or pharmaceuticals, which could make it difficult for us to stop the infringement of our patents. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

The intellectual property protection for our product candidates depends on third parties.

With respect to Lymphoseek, NAV4694, NAV5001 and RIGScan, we have exclusively licensed certain issued patents and pending patent applications covering the respective technologies underlying these product candidates and their commercialization and use and we have licensed certain issued patents and pending patent applications directed to product compositions and chemical modifications used in product candidates for commercialization, and the use and the manufacturing thereof.

The patents and pending patent applications underlying our licenses do not cover all potential product candidates, modifications and uses. In the case of patents and patent applications licensed from AstraZeneca, we have limited control over the filing, prosecution or enforcement of these patents or patent applications. In the case of patents and patent applications licensed from the University of California, San Diego (UCSD), we did not have any control over the filing of the patents and patent applications before the effective date of the Lymphoseek license, and have had limited control over the filing and prosecution of these patents and patent applications after the effective date of the Lymphoseek license. Under certain circumstances, we also have the right to enforce patents and patent applications licensed from AstraZeneca and Alseres. We cannot be certain that such prosecution efforts have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents. We also cannot be assured that our licensors or their respective licensing partners will agree to enforce any such patent rights at our request or devote sufficient efforts to attain a desirable result. Any failure by our licensors or any of their respective licensing partners to properly protect the intellectual property rights relating to our product candidates could have a material adverse effect on our financial condition and results of operation.

We may become involved in disputes with AstraZeneca, UCSD, Alseres, the National Institutes of Health (NIH) or potential future collaborators over intellectual property ownership, and publications by our research collaborators and scientific advisors could impair our ability to obtain patent protection or protect our proprietary information, which, in either case, could have a significant effect on our business.

Inventions discovered under research, material transfer or other such collaborative agreements may become jointly owned by us and the other party to such agreements in some cases and the exclusive property of either party in other cases. Under some circumstances, it may be difficult to determine who owns a particular invention, or whether it is

jointly owned, and disputes could arise regarding ownership of those inventions. These disputes could be costly and time consuming and an unfavorable outcome could have a significant adverse effect on our business if we were not able to protect our license rights to these inventions. In addition, our research collaborators and scientific advisors generally have contractual rights to publish our data and other proprietary information, subject to our prior review. Publications by our research collaborators and scientific advisors containing such information, either with our permission or in contravention of the terms of their agreements with us, may impair our ability to obtain patent protection or protect our proprietary information, which could significantly harm our business.

Our ability to raise capital may be limited by applicable laws and regulations.

Our ability to raise additional capital through the sale and issuance of our equity securities may be limited by, among other things, current Securities and Exchange Commission (Commission) and NYSE MKT rules and regulations. Our capital raising plans include primary offerings of equity securities using a "shelf" registration on Form S-3, which typically enables an issuer to raise additional capital on a more timely and cost effective basis than through other means, such as registration of a securities offering under a Form S-1 registration statement. Under current Commission rules and regulations, to be eligible to use a Form S-3 registration statement for primary offerings without restriction as to the amount of securities to be sold and issued, an issuer must, among other requirements, have outstanding common equity with a market value of at least $75 million held by non-affiliates. Although we currently have outstanding common equity with a market value of significantly more than $75 million held by non-affiliates, if we file a "shelf" Form S-3 registration statement at a time when the aggregate market value of our common stock held by non-affiliates, or public float, is less than $75 million (calculated as set forth in Form S-3 and Commission rules and regulations), the amount we could raise through primary offerings of our securities in any 12-month period using the Form S-3 registration statement may be limited to an aggregate of one-third of our public float. Moreover, the market value of all securities sold by us under a Form S-3 registration statement during the prior 12 months may be subtracted from that amount to determine the amount we can then raise under the Form S-3 registration statement. The Commission's rules and regulations require that we periodically re-evaluate the value of our public float. If, at a re-evaluation date, our public float is less than $75 million, the amount we could raise through primary offerings of our securities in any 12-month period using a Form S-3 registration statement would be subject to the one-third of public float limitation described above.

In addition, under current Commission rules and regulations, if our public float is less than $75 million or if we seek to register a resale offering (i.e., an offering of our securities by persons other than us), we must, among other requirements, maintain our listing with the NYSE MKT or have our common stock listed and registered on another national securities exchange in order to be eligible to use a Form S-3 registration statement for any primary or resale offering. Alternative means of raising capital through sales of our securities, including through the use of a Form S-1 registration statement, may be more costly and time-consuming.

Currently, our common stock is listed on the NYSE MKT. The NYSE MKT will review the appropriateness of continued listing of any issuer that falls below the exchange's continued listing standards. For additional information regarding this risk, see the risk factor below titled "Our failure to maintain continued compliance with the listing requirements of the NYSE MKT could result in the delisting of our common stock." If our common stock were delisted from the NYSE MKT, our ability to raise capital on terms and conditions we deem acceptable, if at all, may be materially impaired.

Our ability to timely raise sufficient additional capital also may be limited by the NYSE MKT's requirements relating to stockholder approval for transactions involving the issuance of our common stock or securities convertible into our common stock. For instance, the NYSE MKT requires that we obtain stockholder approval of any transaction involving the sale, issuance or potential issuance by us of our common stock (or securities convertible into our

common stock) at a price less than the greater of book or market value, which (together with sales by our officers, directors and principal stockholders) equals 20% or more of our presently outstanding common stock, unless the transaction is considered a “public offering” by the NYSE MKT staff. Based on our outstanding common stock as of September 24, 2012 and the average closing price of $3.51 over the thirty trading days preceding September 24, 2012, we could not raise more than approximately $75 million without stockholder approval, unless the transaction is deemed a public offering or does not involve the sale, issuance or potential issuance by us of our common stock (or securities convertible into our common stock) at a price less than the greater of book or market value. However, certain prior sales by us may be aggregated with any offering we may propose in the near-term, further limiting the amount we could raise in any future offering that is not considered a public offering by the NYSE MKT staff and would involve the sale, issuance or potential issuance by us of our common stock (or securities convertible into our common stock) at a price less than the greater of book or market value. The NYSE MKT will also require stockholder approval if the issuance or potential issuance of additional shares will be considered by the exchange staff to result in a change of control of Navidea.

Obtaining stockholder approval is a costly and time-consuming process. If we are required to obtain stockholder approval, we would expect to spend substantial additional money and resources. In addition, seeking stockholder approval would delay our receipt of otherwise available capital, which may materially and adversely affect our ability to execute our current business strategy, and there is no guarantee our stockholders ultimately would approve a proposed transaction. A public offering under the NYSE MKT rules typically involves broadly announcing the proposed transaction, which often has the effect of depressing the issuer's stock price. Accordingly, the price at which we could sell our securities in a public offering may be less and the dilution existing stockholders experience may in turn be greater than if we were able to raise capital through other means.

Our secured 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 (Loan Agreement) with Hercules Technology II. LP (Hercules). 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 borrowed funds when due;
- we keep reserved out of our authorized shares of common stock sufficient shares to satisfy our obligation to issue shares on conversion of the debt and the exercise of the warrants issued in connection with the Loan Agreement; and
- we indemnify Hercules against certain liabilities.

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, capital leases, or contingent obligations outside the ordinary course of business;
- granting or permitting liens against or security interests in our assets;
- acquiring or making investments in any other person other than permitted investments;
- making any material dispositions of our assets outside the ordinary course of business; 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 Hercules to accelerate the maturity of the debt and to sell the assets securing it. Such actions by Hercules could materially adversely affect our operations, results of operations and financial condition, including causing us to substantially curtail our product development activities.

Due to the extension of the PDUFA date for Lymphoseek to September 10, 2012, we did not receive FDA approval of Lymphoseek by the June 30, 2012 deadline established in the Loan Agreement with Hercules, and therefore expect that additional loan proceeds of up to $3 million thereunder will not be available to us under the current terms.

The price of our common stock has been highly volatile due to several factors that will continue to affect the price of our stock.

Our common stock traded as low as $2.05 per share and as high as $4.77 per share during the 12-month period ended September 24, 2012. The market price of our common stock has been and is expected to continue to be highly volatile. Factors, including announcements of technological innovations by us or other companies, regulatory matters, new or existing products or procedures, concerns about our financial position, operating results, litigation, government regulation, developments or disputes relating to agreements, patents or proprietary rights, may have a significant impact on the market price of our stock. In addition, potential dilutive effects of future sales of shares of common stock by the Company and by stockholders, and subsequent sale of common stock by the holders of warrants and options could have an adverse effect on the market price of our shares.

Some additional factors which could lead to the volatility of our common stock include:

- price and volume fluctuations in the stock market at large or of companies in our industry which do not relate to our operating performance;
- changes in securities analysts' estimates of our financial performance or deviations in our business and the trading price of our common stock from the estimates of securities analysts;
- FDA or international regulatory actions and regulatory developments in the U.S. and foreign countries;
- financing arrangements we may enter that require the issuance of a significant number of shares in relation to the number of shares currently outstanding;
- public concern as to the safety of products that we or others develop;
- activities of short sellers in our stock; and
- fluctuations in market demand for and supply of our products.

The realization of any of the foregoing could have a dramatic and adverse impact on the market price of our common stock. In addition, class action litigation has often been instituted against companies whose securities have experienced substantial decline in market price. Moreover, regulatory entities often undertake investigations of investor transactions in securities that experience volatility following an announcement of a significant event or condition. Any such litigation brought against us or any such investigation involving our investors could result in substantial costs and a diversion of management's attention and resources, which could hurt our business, operating results and financial condition.

An investor's ability to trade our common stock may be limited by trading volume.

Historically, the trading volume for our common stock has been relatively limited. The average daily trading volume for our common stock on the OTC Bulletin Board for the 12-month period ended January 31, 2011 was approximately 194,000 shares. Following the listing of our common stock on the NYSE MKT on February 10, 2011, trading in our common stock has been more active. During the 12-month period beginning on September 25, 2011 and ending on September 24, 2012, the average daily trading volume for our common stock on the NYSE MKT was approximately 700,000 shares. We cannot, however, assure you that this trading volume will be consistently maintained in the future.

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

On July 31, 2012, we agreed to issue 300,000 shares of our common stock to Alseres Pharmaceuticals, Inc. (Alseres) as partial payment of a sublicense fee in consideration for a sublicense granted by Alseres. The issuance of the shares was exempt from registration under Section 4(a)(2) of the Securities Act. A registration statement registering these shares for resale by Alseres was declared effective by the U.S. Securities and Exchange Commission on October 17, 2012.

Item 6. Exhibits

31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*
32.1	Certification of Chief Executive Officer of Periodic Financial Reports pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350.**
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.**
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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)
Dated: November 9, 2012

By: /s/ Mark J. Pykett
Mark J. Pykett, V.M.D.,
Ph.D.
President and Chief
Executive Officer
(duly authorized officer;
principal executive officer)

By: /s/ Brent L. Larson
Brent L. Larson
Senior Vice President and
Chief Financial Officer
(principal financial and
accounting officer)

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