NAVIDEA BIOPHARMACEUTICALS, INC.
Form 10-Q
May 10, 2012

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 March 31, 2012

or

¨ **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 (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes x No ¨

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

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange 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: 96,502,330 shares of common stock, par value $.001 per share (as of the close of business on May 4, 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

	March 31, 2012 (unaudited)	December 31, 2011
ASSETS		
Current assets:		
Cash	$21,904,068	$28,644,004
Accounts receivable, net	25,818	15,794
Inventory	918,500	821,549
Prepaid expenses and other	662,534	565,174
Total current assets	23,510,920	30,046,521
Property and equipment	1,539,572	1,441,229
Less accumulated depreciation and amortization	968,795	977,960
	570,777	463,269
Patents and trademarks	106,592	106,592
Less accumulated amortization	21,171	21,171
	85,421	85,421
Other assets	561,783	598,709
Total assets	$24,728,901	$31,193,920

Continued

Navidea Biopharmaceuticals, Inc. and Subsidiaries

Consolidated Balance Sheets, continued

	March 31, 2012 (unaudited)	December 31, 2011
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$791,989	$681,754
Accrued liabilities and other	1,710,901	2,097,786
Note payable to investor, net of discount of $252,646, current	1,661,681	—
Derivative liabilities, current	753,014	568,930
Total current liabilities	4,917,585	3,348,470
Note payable to investor, net of discounts of $237,052 and $543,612, respectively	4,848,621	6,456,388
Other liabilities	253,842	257,315
Total liabilities	10,020,048	10,062,173
Commitments and contingencies		
Stockholders' equity:		
Preferred stock; $.001 par value; 5,000,000 shares authorized; 9,083 Series B shares and 1,000 Series C shares issued and outstanding at March 31, 2012 and December 31, 2011	10	10
Common stock; $.001 par value; 200,000,000 shares authorized; 96,172,330 and 95,398,961 shares issued and outstanding at March 31, 2012 and December 31, 2011, respectively	96,172	95,399
Additional paid-in capital	266,984,050	266,393,645
Accumulated deficit	(252,371,379)	(245,357,307)
Total stockholders' equity	14,708,853	21,131,747
Total liabilities and stockholders' equity	$24,728,901	$31,193,920

See accompanying notes to consolidated financial statements

Navidea Biopharmaceuticals, Inc. and Subsidiaries

Consolidated Statements of Operations and Comprehensive Loss

(unaudited)

	Three Months Ended March 31,	
	2012	2011
Grant revenue	$11,931	$335,962
Operating expenses:		
Research and development	3,943,714	2,435,598
Selling, general and administrative	2,574,630	2,901,707
Total operating expenses	6,518,344	5,337,305
Loss from operations	(6,506,413)	(5,001,343)
Other income (expense):		
Interest income	9,733	3,519
Interest expense	(293,671)	(1,607)
Change in derivative liabilities	(184,084)	(953,789)
Other	(14,637)	(713)
Total other expense, net	(482,659)	(952,590)
Loss before income taxes	(6,989,072)	(5,953,933)
Benefit from income tax	—	520,813
Loss from continuing operations	(6,989,072)	(5,433,120)
Discontinued operations–income from operations, net of tax effect	—	1,010,991
Net loss and comprehensive loss	(6,989,072)	(4,422,129)
Preferred stock dividends	(25,000)	(25,000)
Net loss and comprehensive loss attributable to common stockholders	$(7,014,072)	$(4,447,129)
Loss per common share (basic and diluted):		
Continuing operations	$(0.07)	$(0.06)
Discontinued operations	$—	$0.01
Attributable to common stockholders	$(0.07)	$(0.05)
Weighted average shares outstanding:		

Basic and diluted	94,074,918	85,416,015

See accompanying notes to 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	—	—	350,000	350	—	—	350
Cancelled restricted stock	—	—	(4,500)	(5)	5	—	—
Issued stock upon exercise of stock options, net	—	—	427,869	428	172,096	—	172,524
Stock compensation expense	—	—	—	—	418,304	—	418,304
Preferred stock dividends	—	—	—	—	—	(25,000)	(25,000)
Net loss	—	—	—	—	—	(6,989,072)	(6,989,072)
Balance, March 31, 2012	10,083	$ 10	96,172,330	$96,172	$266,984,050	$(252,371,379)	$14,708,853

See accompanying notes to consolidated financial statements.

Navidea Biopharmaceuticals, Inc. and Subsidiaries

Consolidated Statements of Cash Flows

(unaudited)

	Three Months Ended March 31,	
	2012	2011
Cash flows from operating activities:		
Net loss	$(6,989,072)	$(4,422,129)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	33,919	59,597
Loss on disposal and abandonment of assets	—	14,144
Amortization of debt discount and debt offering costs	116,314	—
Stock compensation expense	418,304	1,004,825
Change in derivative liabilities	184,084	953,789
Issuance of common stock to 401(k) Plan	—	48,289
Changes in operating assets and liabilities:		
Accounts receivable	(587)	223,203
Inventory	(96,951)	(57,017)
Prepaid expenses and other assets	(132,270)	79,645
Accounts payable	110,236	(664,242)
Accrued liabilities and other liabilities	(235,099)	812,092
Deferred revenue	—	158,215
Net cash used in operating activities	(6,591,122)	(1,789,589)
Cash flows from investing activities:		
Purchases of equipment	(141,427)	(56,625)
Patent and trademark costs	—	(4,660)
Net cash used in investing activities	(141,427)	(61,285)
Cash flows from financing activities:		
Proceeds from issuance of common stock	177,669	5,189,262
Payment of tax withholdings related to stock-based compensation	(4,795)	—
Payment of preferred stock dividends	(25,000)	(25,000)
Payment of debt issuance costs	(153,949)	—
Payment of notes payable	—	(26,437)
Payments under capital leases	(1,312)	(3,029)
Net cash (used in) provided by financing activities	(7,387)	5,134,796
Net (decrease) increase in cash	(6,739,936)	3,283,922

Cash, beginning of period	28,644,004	6,420,506
Cash, end of period	$21,904,068	$9,704,428

See accompanying notes to consolidated financial statements.

Notes to Consolidated Financial Statements

(unaudited)

1. Summary of Significant Accounting Policies

a. **Basis of Presentation:** The information presented as of March 31, 2012 and for the three-month periods ended March 31, 2012 and March 31, 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 March 31, 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 sheets 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 March 31, 2012 and December 31, 2011 is presented as the face amount of the note less unamortized discounts. At March 31, 2012, the carrying value of the note payable to investor is approximately $6.5 million, which approximates fair 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 March 31, 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 9.

2. Discontinued Operations

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.

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 $30.1 million.

As a result of the sale of the GDS Business and discontinuing operations of our Cardiosonix subsidiary, we reclassified revenues and expenses related to the GDS Business and our Cardiosonix subsidiary to discontinued operations for 2011. The following amounts have been segregated from continuing operations and included in discontinued operations in the consolidated statements of operations:

	Three Months Ended March 31, 2011

Net sales	$ 2,535,839
Cost of goods sold	758,613
Gross profit	1,777,226
Operating expenses:	
Research and development	176,086
Selling, general and administrative	69,202
Total operating expenses	245,288
Other expense, net	(134)
Income taxes	(520,813)
Income from discontinued operations	$ 1,010,991

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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 March 31, 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 March 31, 2012
Liabilities:				
Derivative liabilities related to warrants, current	$ —	$ 753,014	$ —	$ 753,014

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 periods ended March 31, 2012 and 2011. There were no transfers in or out of our Level 2 liabilities during the three-month period ended March 31, 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 three-month period ended March 31, 2011. See Note 9.

4. Stock-Based Compensation

At March 31, 2012, we have instruments outstanding under two stock-based compensation plans; the 1996 Stock Incentive Plan (the 1996 Plan) and the Third 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 10 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 generally vest upon occurrence of a specific event or achievement of goals as defined in the grant agreements. As a result, 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 March 31, 2012 and 2011, our total stock-based compensation expense was approximately $418,000 and $1.0 million, respectively. Stock-based compensation expense for the first quarter of 2011 included approximately $718,000 of accrued expense related to the separation of our former President and CEO, David C. Bupp. (See Note 7.) We have not recorded any income tax benefit related to stock-based compensation in either of the three-month periods ended March 31, 2012 and 2011.

A summary of the status of our stock options as of March 31, 2012, and changes during the three-month period then ended, is presented below:

	Three Months Ended March 31, 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	969,013	3.23		
Exercised	(431,668)	0.42		
Forfeited	(7,332)	1.75		
Expired	—	—		
Outstanding at end of period	3,845,013	$ 1.64	5.8 years	$6,470,392
Exercisable at end of period	2,239,767	$ 0.75	3.2 years	$5,672,876

A summary of the status of our unvested restricted stock as of March 31, 2012, and changes during the three-month period then ended, is presented below:

	Three Months Ended March 31, 2012	
	Number of Shares	Weighted Average Grant-Date Fair Value
Unvested at beginning of period	1,556,000	$ 2.48
Granted	300,000	3.28
Vested	—	—
Forfeited	—	—
Expired	—	—
Unvested at end of period	1,856,000	$ 2.61

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As of March 31, 2012, there was approximately $2.9 million of total unrecognized compensation expense related to unvested stock-based awards, which we expect to recognize over remaining weighted average vesting terms of 2.1 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 periods ended March 31, 2012 and 2011:

	Basic and Diluted Earnings Per Share Three Months Ended March 31,	
	2012	2011
Outstanding shares	96,172,330	89,137,675
Effect of weighting changes in outstanding shares	(241,412)	(1,335,160)
Unvested restricted stock	(1,856,000)	(2,386,500)
Adjusted shares	94,074,918	85,416,015

Earnings (loss) per common share for the three-month periods ended March 31, 2012 and 2011 excludes the effects of 55.6 million and 61.6 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 included in the number of shares outstanding for both basic and diluted earnings per share calculations. However, due to our loss from continuing operations, 1,856,000 and 2,386,500 shares of unvested restricted stock were excluded in determining basic and diluted loss per share for the three-month periods ended March 31, 2012 and 2011, respectively, because such inclusion would be anti-dilutive.

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 three-month periods ended March 31, 2012 and 2011, we capitalized $510,000 and $213,000, respectively, of inventory costs associated with our Lymphoseek product. During the three-month period ended March 31, 2012, we wrote off $74,000 of previously capitalized Lymphoseek inventory due to the consumption of the Lymphoseek material in previously unanticipated product development activities.

The components of inventory as of March 31, 2012 and December 31, 2011, net of reserves of $339,000 and $0, respectively, are as follows:

	March 31, 2012 (unaudited)	December 31, 2011
Pharmaceutical materials	$ 746,000	$ 482,000
Pharmaceutical work-in-process	172,500	339,549
Total	$ 918,500	$ 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 three-month period ended March 31, 2012, we recorded an obsolescence reserve for $339,000 of Lymphoseek inventory due to changes in our projections of the probability of future commercial use for the specific lots previously capitalized.

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 March 31, 2012 and December 31, 2011, including employer payroll tax obligations, related to the provisions of Mr. Bupp's separation agreement:

	March 31, 2012 (unaudited)	December 31, 2011
Separation	$ 45,012	$ 180,074
Pro-rated 2011 bonus	—	60,870
Estimated continuing healthcare coverage	59,064	61,875
	$ 104,076	$ 302,819

8. Convertible Securities

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 March 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, pursuant to the terms of the Loan Agreement, if the U.S. Food and Drug Administration (FDA) approval of Lymphoseek occurs on or before June 30, 2012, Navidea has the option to draw a second advance in the principal amount of $3,000,000 (the Second Advance), bearing interest at the same rate and payable on the same terms as the First Advance. The Loan Agreement provides for an interest-only period beginning on December 29, 2011 and expiring on July 1, 2012, provided the interest-only period shall expire on January 1, 2013 upon Navidea's receipt of FDA approval for Lymphoseek on or before June 30, 2012. The principal and interest is to be repaid in 30 equal monthly installments of principal and interest, payable on the first of each month following the expiration of the interest-only period. The outstanding balance of the debt is due December 1, 2014, or June 1, 2015 if the interest-only period is extended following FDA approval of Lymphoseek. 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 March 31, 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. As a result, we recorded a derivative liability with an estimated fair value of $520,478 on the date of issuance of the Series GG Warrant, which was recorded as a discount on the First Advance. Navidea incurred total debt issuance costs of $593,339 including origination, legal, and other costs related to the loan. The total aggregate discounts on the First Advance of $545,366 and the debt issuance costs of $593,339 are being amortized as non-cash interest expense using the effective interest method over the term of the Loan Agreement.

During the three-month period ended March 31, 2012, we recorded interest expense of $116,000 related to amortization of the debt discounts and deferred financing costs related to our convertible note.

In April 2012, we were notified by FDA that our Prescription Drug User Fee Act (PDUFA) date for Lymphoseek has been modified to September 10, 2012, a 90-day extension from the initial PDUFA date of June 10, 2012. Due to the extension of the PDUFA date, we do not expect to receive FDA approval of Lymphoseek by the June 30, 2012 deadline established in the Loan Agreement. Therefore, we may not be able to draw the Second Advance under the current terms, and the interest-only period on the First Advance will expire on July 1, 2012. As such, we have reclassified a portion of the principal, net of related discounts, as a current liability as of March 31, 2012.

9. Derivative Instruments

Certain warrants to purchase our common stock are considered derivative liabilities under current accounting standards. Navidea's Series V and 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.

In January 2011, certain Series V warrants were modified to remove the language that had previously required them to be classified as derivative liabilities. As a result of the modification of the Series V warrants, we reclassified $1.4 million in derivative liabilities related to those warrants to additional paid-in capital during the first quarter of 2011. Also in January 2011, certain Series CC and Series DD warrants were modified to remove the language that had

previously required them to be classified as derivative liabilities. As a result of the modification of the Series CC and Series DD warrants, we reclassified $549,000 in derivative liabilities related to those warrants to additional paid-in capital during the first quarter of 2011.

During the first quarter of 2011, certain outside investors exercised 1,578,948 Series CC warrants, 799,474 Series DD warrants, and 60,000 Series Z warrants, resulting in reclassification of $1.3 million in derivative liabilities related to those warrants to additional paid-in capital during the first quarter of 2011.

The net effect of marking the Company's derivative liabilities to market during the three-month periods ended March 31, 2012 and 2011 resulted in net increases in the estimated fair values of the derivative liabilities of approximately $184,000 and $954,000, respectively, which were recorded as non-cash expense. The total estimated fair value of the remaining derivative liabilities was $753,000 and $569,000 as of March 31, 2012 and December 31, 2011, respectively.

10. Stock Warrants

During the first quarter of 2011, certain outside investors exercised 1,578,948 Series CC warrants in exchange for issuance of 1,578,948 shares of our common stock, resulting in gross proceeds of $3,331,580. Also during the first quarter of 2011, certain outside investors exercised 799,474 Series DD warrants in exchange for issuance of 799,474 shares of our common stock, resulting in gross proceeds of $1,686,890. In addition, another outside investor exercised 60,000 Series Z warrants on a cashless basis in exchange for issuance of 46,902 shares of our common stock during the first quarter of 2011.

At March 31, 2012, there are 17.6 million warrants outstanding to purchase our common stock. The warrants are exercisable at prices ranging from $0.31 to $2.375 per share with a weighted average exercise price of $0.56 per share.

11. 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 March 31, 2012 and December 31, 2011. An estimated provision for income taxes of $521,000 related to income from discontinued operations was offset by the estimated tax benefit related to the loss from continuing operations during the first quarter of 2011.

Current accounting standards include guidance on the accounting for uncertainty in income taxes recognized in the financial statements. Such standards also prescribe a recognition threshold and measurement model for the financial statement recognition of a tax position taken, or expected to be taken, and provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. The Company believes that the ultimate deductibility of all tax positions is highly certain, although there is uncertainty about the timing of such deductibility. As a result, no liability for uncertain tax positions was recorded as of March 31, 2012 or December 31, 2011 and we do not expect any significant changes in the next twelve months. Should we need to accrue interest or

penalties on uncertain tax positions, we would recognize the interest as interest expense and the penalties as a selling, general and administrative expense. As of March 31, 2012, tax years 2008-2011 remained subject to examination by federal and state tax authorities.

12. Supplemental Disclosure for Statements of Cash Flows

During the three-month periods ended March 31, 2012 and 2011, we paid interest aggregating $123,000 and $2,000, respectively. During the three-month period ended March 31, 2011, we issued 30,438 shares of our common stock as matching contributions to our 401(k) plan. During the three-month period ended March 31, 2011, we transferred $23,000 of GDS Business inventory to fixed assets related to the creation and maintenance of a pool of service loaner equipment.

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 three radiopharmaceutical agent platforms. The first, Lymphoseek® (Kit for the Preparation of 99m-Tc-Tilmanocept for Injection), is intended to be used to assess the spread of certain solid tumor cancers into the lymphatic system. The second, AZD4694, is intended to aid in the imaging and evaluation of patients with signs or symptoms of cognitive impairment such as Alzheimer's disease (AD). The third, RIGScan™, is intended to be used 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 two radiopharmaceutical platforms within oncology, Lymphoseek and RIGScan. 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 AZD4694 and RIGScan, and sourcing and development of additional radiopharmaceutical 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 have been 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 B. Komen Breast Cancer Research Foundation have been published in leading medical journals including Journal of Nuclear Medicine and Annals of Surgical Oncology. Clinical research continues with an ongoing Phase 3 trial involving subjects with head and neck squamous cell carcinoma.

Lymphoseek development has involved periodic interaction with and feedback from the U.S. Food and Drug Administration (FDA). In early 2005, the UCSD physician Investigational New Drug (IND) application was transferred to Navidea and we assumed full clinical and commercial responsibility for the development of Lymphoseek. Following the establishment of the corporate IND, Navidea began discussions with FDA regarding the clinical development program for Lymphoseek. Additional non-clinical testing was successfully completed in late 2005 and reports were filed with FDA in December 2005. These studies included repeat administrations of Lymphoseek at dosages significantly in excess of the anticipated clinical dosage. None of the non-clinical studies revealed any toxicity issues associated with the drug.

Upon the submission of the IND and draft Phase 2 protocol, FDA advised Navidea that commercially-produced Lymphoseek would need to be used in the Phase 2 clinical study, as opposed to using drug previously manufactured in laboratories at UCSD. Navidea transferred bulk drug manufacturing to Reliable Biopharmaceutical Corporation (Reliable) and engaged OSO BioPharmaceuticals Manufacturing LLC (OSO Bio, formerly Cardinal Health PTS) for commercial manufacturing of the drug product.

We received clearance from FDA in May 2006 to move forward with patient enrollment for a multi-center Phase 2 clinical study of Lymphoseek and began patient enrollment in September 2006. Enrollment of 80 patients was completed in June 2007 and we announced positive efficacy and final results in June and December 2007, respectively. Localization of Lymphoseek to lymphoid tissue was confirmed by pathology in over 99% of the lymph node tissue samples removed during the Phase 2 trial. We held an end of Phase 2 meeting with FDA during late October 2007 and results of the study were published in the February 2011 online edition of the *Annals of Surgical Oncology*.

During 2008, we initiated patient enrollment in a Phase 3 clinical study in subjects with either breast cancer or melanoma (NEO3-05). In March 2009, we announced that this study had reached the accrual of 203 lymph nodes, the

study's primary accrual objective. The NEO3-05 Phase 3 clinical study was an open label trial of node-negative subjects designed to evaluate the safety and the accuracy of Lymphoseek in identifying the lymph nodes draining from the subject's primary tumor site. The primary efficacy objective of the study was a statistically acceptable concordance rate between the identification of lymph nodes with vital blue dye (VBD) and Lymphoseek. In addition, a secondary endpoint of the study was a pathological assessment of the ability of VBD and Lymphoseek to identify lymph nodes that contain cancer.

In June 2009, we initiated a second Phase 3 trial in subjects with head and neck squamous cell carcinoma (NEO3-06). The NEO3-06 study was designed to expand the potential labeling for Lymphoseek to include a sentinel lymph node targeting claim, intended to follow an initial marketing clearance for general lymphatic mapping. The accrual rate for this trial is slower than for the NEO3-05 and NEO3-09 trials due in part to the lower incidence rate for head and neck cancers for subjects eligible for this trial.

In March 2010, Navidea met with FDA to review the clinical outcomes of the NEO3-05 Phase 3 trial. The meeting included a review of the efficacy and safety results of the study and Navidea's plans for the submission of a New Drug Application (NDA) for Lymphoseek based on the results of NEO3-05 and other previously completed clinical studies. In July 2010, Navidea initiated enrollment in another Phase 3 clinical evaluation of Lymphoseek in subjects with either breast cancer or melanoma (NEO3-09), primarily intended for the purpose of augmenting the safety population and supporting potential expanded product labeling claims. Based on guidance received in the March 2010 meeting, we planned to file data related to the NEO3-09 trial as part of a planned major amendment to the primary NDA.

In October 2010, Navidea met with FDA for a pre-NDA assessment for Lymphoseek. As a result of the pre-NDA assessment, FDA requested that data from both the completed NEO3-05 study and the NEO3-09 study then in progress be included in the Company's primary NDA for Lymphoseek rather than submitting the NEO3-09 study data as a planned major amendment to the ongoing NDA review, as initially intended by the Company. The pre-NDA assessment resulted in no modification to the NEO3-09 trial design or endpoints or to any of the other previously agreed-to clinical or regulatory components of the Lymphoseek NDA.

In February 2011, we announced that we had accrued an adequate number of subjects to enable us to meet the lymph node accrual goal for NEO3-09. Top-line data from NEO3-09 were released during the second quarter of 2011, indicating that all primary and secondary endpoints for the study were met and demonstrating strong agreement with the previously successful NEO3-05 clinical study. Navidea submitted the NDA for Lymphoseek in August 2011, and was notified of acceptance of the NDA by FDA in October 2011. The Lymphoseek NDA submission was based on the clinical results of the NEO3-05 and NEO3-09 Phase 3 clinical studies and other completed clinical and non-clinical evaluations. The safety database submitted with the NDA included data from over five hundred subjects and identified no significant drug-related adverse events.

In the letter from FDA notifying the Company of the acceptance of the Lymphoseek NDA, FDA originally established a Prescription Drug User Fee Act (PDUFA) date for Lymphoseek of June 10, 2012. In April 2012, we were notified by FDA that the Agency had elected to modify the PDUFA date for Lymphoseek to September 10, 2012, a 90-day extension from the initial PDUFA date of June 10, 2012, based on updated chemistry, manufacturing and control (CMC) information the Company had filed with the Agency in response to a request from FDA. Neither this FDA decision nor the NDA review to date has raised questions on Lymphoseek's safety or efficacy, or the design of the clinical trials supporting registration. Depending on the timing and outcome of the FDA regulatory review cycle, we believe that Lymphoseek can be commercially launched in the fourth quarter of 2012, although given the nature of the FDA review process, we cannot assure you that we will not experience further delays.

As noted above, our third Phase 3 clinical trial for Lymphoseek in subjects with head and neck squamous cell carcinoma (NEO3-06) is currently in progress. The NEO3-06 clinical study was designed to expand the potential product label for Lymphoseek as a sentinel lymph node biopsy agent after the initial marketing clearance for the product. We believe we may reach a patient accrual point by mid-2012 that would enable an interim analysis of the trial data. Further, we do not believe the Lymphoseek PDUFA date extension pertains in any way to the NEO3-06 trial, nor do we believe analysis of the interim data will be completed prior to the September 10th PDUFA date.

Navidea was also advised in February 2012 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 Authorization Application (MAA) submission based on clinical data accumulated from clinical studies completed to date and supporting clinical literature. As such, we intend to submit our MAA to the EMA by the end of 2012.

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.

AZD4694

AZD4694 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 positron emission tomography (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, AZD4694 appears to have better sensitivity 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 sensitivity and contrast may allow detection of smaller amounts of amyloid and may enable earlier identification of disease, as well as providing the opportunity to detect smaller changes in amyloid levels in monitoring disease progression over time.

AZD4694 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 AZD4694 has the potential ability to image patients quickly and safely with high sensitivity.

We are currently supporting ongoing Phase 2 clinical trials and advancing our development plans for AZD4694. We expect to initiate new Phase 2 trials in 2012, primarily to expand the safety database for the compound, and a Phase 3 trial in 2013 to support registration in the U.S. and the EU, upon completion of certain preparatory CMC activities. We cannot assure you, however, 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.

RIGScan

RIGS® is a technique to provide real-time 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, administered prior to surgery and identified during surgery with a gamma detection device/probe. This procedure assists a surgeon in identifying the location of cancerous tissues in real time (during surgery) to enable more thorough surgical removal for better patient outcomes. 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 a gamma probe and direct

the surgeon to targeted tissue for removal.

RIGScan development to date has been based on an intraoperative biologic targeting agent consisting of a radiolabeled murine monoclonal antibody (CC49 MAb, Minretumomab). The CC49 MAb localizes or binds to TAG-72 antigen expressed on a variety of 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.

RIGScan has been studied in several clinical trials, including Phase 3 studies. Results from certain of these studies have been published in leading cancer journals including Clinical Cancer Research, Annals of Surgical Oncology and Disease of the Colon and Rectum. Navidea conducted two Phase 3 studies, NEO2-13 and NEO2-14, of RIGScan in the mid-1990s in patients with primary and metastatic colorectal cancer, respectively. Both studies were multi-institutional involving cancer treatment institutions in the U.S., Israel, and the EU.

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 NEO2-14, considered by the Company to be the pivotal study in support of the RIGScan Biologic License Application (BLA). Following review of our applications, we received requests for further information from FDA and from the European Committee for Proprietary Medicinal Products on behalf of EMA. Both FDA and EMA acknowledged that our studies met the diagnostic endpoint of the Phase 3 clinical study, which was to provide incremental information to the surgeon regarding the location of hidden tumor. However, both agencies focused on potential clinical benefits that altered the management or therapeutic outcome of patients with metastatic colorectal cancer. FDA determined during its review of the BLA that in addition to identifying additional pathology-confirmed disease, the clinical studies of RIGScan needed to demonstrate clinical utility in enhancing patient outcomes, an outcome measure which the completed studies were not designed to address. Navidea withdrew its application to EMA in November 1997.

We continued over the intervening years to identify a pathway to regulatory approval for RIGScan. Despite additional data developed subsequent to the BLA filings, including data in 2004 indicating that RIGScan status was correlated with patient survival trends and that RIGScan may be predictive of a positive outcome when measuring survival of the patients that participated in our original BLA studies, and submission of an IND amendment to FDA which included the design of a proposed Phase 3 clinical trial of RIGScan, we were not able to advance RIGScan in clinical development or through the regulatory review process.

To further support resumed RIGScan development, we filed a new IND request for the biologic component of the RIGS technology in late 2010. We held a pre-IND meeting with FDA in February 2011 to define the basic CMC requirements needed to resume clinical development efforts on RIGScan. FDA reviewed Navidea’s comprehensive pre-IND package and provided direction to the Company on its clinical and manufacturing activities going forward. As an outcome of the pre-IND meeting, 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 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 transitioned from a murine antibody to a humanized antibody.

To recommence developement, we have focused initially on manufacturing the humanized antibody with the aim of completing the necessary manufacturing steps to permit active clinical development by the end of 2012; however, as management continues to assess the scope and required resources for the RIGS program, particularly in light of other development opportunities such as for AZD4694 or other agents, the timing and scope of our development and commercialization plan for RIGScan may be affected.

It should also be noted that the RIGScan biologic drug 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 manufacturing and radiolabeling capabilities for the antibody in order to meet the regulatory needs for the RIGScan product.

We continue to believe it may be appropriate for us to identify a development partner for RIGScan. We have engaged in discussions with various parties over the past few years regarding potential partnerships and/or other development arrangements. However, even if we are able to make such arrangements on satisfactory terms, we believe that the time required for continued development, regulatory approval and commercialization of a RIGS 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.

[^{123}I]-E-IACFT (Under Option)

In January 2012, we executed an option agreement with Alseres Pharmaceuticals, Inc. to license [^{123}I]-E-IACFT Injection, an Iodine-123 radiolabeled imaging agent being developed as an aid in the diagnosis of Parkinson's disease, movement disorders and dementia. The option agreement provides Navidea with exclusive rights for a period of up to six months to perform final due diligence and prepare the documentation necessary to enter into a definitive license agreement for [^{123}I]-E-IACFT. Under the terms of the option agreement, Navidea paid Alseres an option fee of $500,000 for the exclusive right to negotiate a definitive license agreement by June 30, 2012. Navidea can extend the option period from June 30, 2012, to July 31, 2012, for an additional $250,000. The option agreement anticipates that Navidea will issue Alseres 400,000 shares of Navidea common stock upon execution of the definitive license agreement. The option also anticipates that the license agreement will provide for contingent milestone payments of up to $3.0 million, $2.75 million of which will occur at the time of product registration or upon commercial sales, and the issuance of up to an additional 1.05 million shares of Navidea stock, 950,000 shares of which are issuable at the time of product registration or upon commercial sales. In addition, the license terms outlined in the option agreement anticipate royalties on net sales of the approved product which are consistent with industry-standard terms.

[^{123}I]-E-IACFT is a patented, novel, small molecule radiopharmaceutical used with single photon emission computed tomography (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.

[^{123}I]-E-IACFT has been administered to over 600 subjects to date. A Phase 3 Special Protocol Assessment (SPA) for [^{123}I]-E-IACFT was granted by FDA in 2009. Results from clinical trials have demonstrated that [^{123}I]-E-IACFT 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, [^{123}I]-E-IACFT may also be useful in the diagnosis of Dementia with Lewy Bodies (DLB), one of the most common forms of dementia after AD.

We are continuing to complete our diligence related to [^{123}I]-E-IACFT in order to enable us to make a decision whether to execute our option to license this product candidate.

Outlook

We spent approximately $3.9 million and $2.4 million on research and development activities during the three-month periods ended March 31, 2012 and 2011, respectively. Following the sale of the GDS Business, our entire organization is now focused on the development of radiopharmaceutical agents that fulfill our vision of becoming a leader in precision diagnostics. 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:

	Three Months Ended March 31,	
Development Program	2012	2011
Lymphoseek	$1,685,784	$1,379,538
AZD4694	155,280	—
RIGScan	320,493	345,598
[^{123}I]-E-IAFCT	582,723	—

Due to the advancement of our efforts with Lymphoseek, AZD4694, RIGScan and potentially other programs, we expect our drug-related development and commercialization expenses to increase in 2012 over 2011.

With respect to Lymphoseek, we were originally notified by FDA that the PDUFA date for Lymphoseek was June 10, 2012. However, as we announced on April 3rd, we were notified by FDA on April 2nd that the Agency had elected to modify the PDUFA date for Lymphoseek has been extended to September 10, 2012, a 90-day extension from the initial PDUFA date of June 10th. Late in the review cycle of the Lymphoseek NDA, FDA had requested updated chemistry, manufacturing and control information related to one of several drug analytical assays. We submitted the requested information on March 30, 2012. As this was within the 90-day period prior to the PDUFA date, FDA elected to extend the review period by 90 days to complete a first-cycle evaluation. Until the NDA review is complete and we reach our new PDUFA date, 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.

Depending on the timing and outcome of the FDA regulatory review cycle, we believe that Lymphoseek can still be commercially launched in 2012. However, we cannot assure you that Lymphoseek will achieve regulatory approval and commercial launch. During 2012, we expect to incur additional development expenses related to supporting the NDA review of Lymphoseek, our preparation to file 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 2012 to support our business development and commercialization activities surrounding Lymphoseek.

We also expect to incur significant expenses during the remainder of 2012 related to preparing for the commencement of additional Phase 2 clinical trials for AZD4694 in 2012 and preparing for the initiation of a pivotal Phase 3 clinical trial in 2013, as well costs for manufacturing-related activities required prior to filing for regulatory clearance to market. AZD4694 is currently not expected to contribute revenue to the Company until 2016 at the earliest.

We are also moving forward with manufacturing activities to support further development of RIGScan. While it is possible that we may be able to complete the necessary manufacturing steps to permit active clinical development of RIGScan by the end of 2012, as management continues to assess the scope and required resources for the RIGS® program, particularly in light of other development opportunities such as for AZD4694 and our option to license

[^{123}I]-E-IACFT, the timing and scope of our development and commercialization plan for RIGScan may be affected. We continue to believe it may be appropriate for us to identify a development partner for RIGScan. We have engaged in discussions with various parties over the past few years regarding potential partnerships and/or other development arrangements. However, even if we are able to make arrangements to support development on satisfactory terms, we believe that the time required for continued development, regulatory approval and commercialization of a RIGS product would likely be a minimum of five years before we receive any significant product-related royalties or revenues.

Finally, if we choose to exercise our option to license [^{123}I]-E-IACFT and are successful in completing a definitive license, or 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 $30.1 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 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.

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 revenue we have received and our operating variances focus on our radiopharmaceutical development programs and the supporting general and administrative expenses.

With respect to our grant revenue, in June 2010, Navidea was notified that Ohio's Third Frontier Commission voted to award a grant of $1 million to fund ongoing development of the Company's Lymphoseek initiative. The grant was used

to accelerate the application of Lymphoseek in head and neck cancer treatment and involved a collaboration of several Ohio-based companies as well as leading cancer centers in the U.S. Navidea and its collaborators were required to contribute an additional $1.1 million in matching funds over the course of the project. We recognized Ohio Third Frontier grant revenue of approximately $592,000 and $358,000 during 2011 and 2010, respectively, and expect to recognize the remaining $50,000 as revenue during 2012. During the three-month period ended March 31, 2012, Navidea recognized an additional $12,000 of miscellaneous grant revenue.

Three Months Ended March 31, 2012 and 2011

Grant Revenue. Grant revenue of $12,000 during the first quarter of 2012 was related to an Ohio Third Frontier grant to support student internships. Grant revenue of $336,000 during the first quarter of 2011 was related to the Ohio Third Frontier grant to support Lymphoseek development.

Research and Development Expenses. Research and development expenses increased $1.5 million, or 62%, to $3.9 million during the first quarter of 2012 from $2.4 million during the same period in 2011. The increase was primarily due to net increases in drug project expenses related primarily to (i) the $500,000 license option fee and $83,000 of due diligence activities related to [^{123}I]-E-IACFT, (ii) a net increase in Lymphoseek development costs including increased manufacturing-related costs of $357,000, the reserve for obsolescence related to previously capitalized Lymphoseek inventory of $339,000, consulting costs related to preparation for a potential FDA Advisory Committee meeting of $319,000, and regulatory consulting costs of $117,000, offset by decreased clinical activity costs of $817,000, (iii) increased AZD4694 development costs including project management and clinical trial development fees of $82,000, consulting costs of $48,000, and manufacturing-related costs of $20,000, and (iv) consulting costs related to potential pipeline products of $119,000; offset by (v) a net decrease in RIGScan development costs including decreased consulting fees of $187,000, offset by increased manufacturing-related costs of $169,000. The net increase in research and development expenses was also due to increased compensation of $187,000 related to increased headcount required for expanded development efforts and other related expenses such as incentive-based compensation, as well as increased costs related to pharmacovigilance activities, recruiting, and travel.

Selling, General and Administrative Expenses. Selling, general and administrative expenses decreased $327,000, or 11%, to $2.6 million during the first quarter of 2012 from $2.9 million during the same period in 2011. The net decrease was primarily due to separation costs of $1.7 million related to the separation of our former President and CEO, David Bupp, offset by increased marketing costs related to the commercial launch of Lymphoseek of $681,000, increased compensation costs of $476,000 related to increased headcount and incentive-based compensation, increased travel, recruiting and other expenses to support the increased headcount of $165,000, and financial advisory fees of $95,000.

Other Income (Expenses). Other expense, net, was $473,000 during the first quarter of 2012 as compared to $953,000 during the same period in 2011. During the first quarter of both 2012 and 2011, we recorded charges of $184,000 and $954,000, respectively, related to the increases in derivative liabilities resulting from the requirement to mark our derivative liabilities to market. Interest expense increased $292,000 to $294,000 during the first quarter of 2012 from $2,000 for the same period in 2011, due to the note payable we entered into in December 2011. Of this interest expense, $116,000 in the first quarter of 2012 was non-cash in nature related to the amortization of debt issuance costs as well as discounts resulting from the warrants issued and conversion features embedded in the note.

Income Taxes. An estimated provision for income taxes of $521,000 related to income from discontinued operations was offset by the estimated tax benefit related to the loss from continuing operations during the first quarter of 2011.

Income from Discontinued Operations. The income from discontinued operations was $1.0 million, net of $521,000 in estimated taxes, during the first quarter of 2011 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 $21.9 million at March 31, 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. The current ratio decreased to 4.8:1 at March 31, 2012 from 9.0:1 at December 31, 2011.

Operating Activities. Cash used in operations increased $4.8 million to $6.6 million during the first quarter of 2012 compared to $1.8 million during the same period in 2011.

Inventory levels increased to $919,000 at March 31, 2012 from $822,000 at December 31, 2011. An increase in pharmaceutical materials was related to completion of a new batch of the Lymphoseek active pharmaceutical

ingredient (API). Pharmaceutical work-in-process decreased related to reserving previously capitalized Lymphoseek inventory due to changes in our projections of the probability of future commercial use, and to the consumption of Lymphoseek inventory for product development activities. We expect inventory levels to increase over the remainder of 2012 as we produce additional drug inventory in anticipation of the Lymphoseek product launch.

Accounts payable increased to $792,000 at March 31, 2012 from $682,000 at December 31, 2011 primarily due to normal fluctuations in timing of receipt and payment of invoices. Accrued liabilities and other decreased to $1.7 million at March 31, 2012 from $2.1 million at December 31, 2011, primarily due to payment of the 2011 bonuses and separation costs related to the separation of our former CEO, David Bupp, during the first quarter of 2012. Our payable and accrual balances will continue to fluctuate but will likely increase overall as we increase our level of development activity related to AZD4694 and other programs.

Investing Activities. Investing activities used $141,000 during the first quarter of 2012 compared to using $61,000 during the same period in 2011. Capital expenditures of $141,000 during the first quarter of 2012 were primarily for software, equipment to be used in the production of Lymphoseek, computers, and furniture and fixtures for the new branch office in Andover, MA. Capital expenditures of $57,000 during the first quarter of 2011 were primarily for computers, equipment to be used in the production of Lymphoseek and gamma detection devices, and software. We expect our overall capital expenditures for the remainder of 2012 will be higher than in 2011. Payments for patent and trademark costs were $5,000 during the first quarter of 2011.

Financing Activities. Financing activities used $7,000 during the first quarter of 2012 compared to $5.1 million provided during the same period in 2011. The $7,000 used by financing activities in the first quarter of 2012 consisted primarily of payments of debt issuance costs of $154,000, payment of preferred stock dividends of $25,000, and payments of capital leases of $1,000, offset by net proceeds from the issuance of common stock of $173,000. The $5.1 million provided by financing activities in the first quarter of 2011 consisted primarily of proceeds from the issuance of common stock of $5.2 million, offset slightly by payments of notes payable of $26,000, preferred stock dividends of $25,000, and capital leases of $3,000.

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 March 31, 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). 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. As a result, we recorded a derivative liability with an estimated fair value of $520,478 on the date of issuance of the Series GG Warrant, which was recorded as a discount on the First Advance. Additionally, pursuant to the terms of the Loan Agreement, if FDA approval of Lymphoseek occurs on or before June 30, 2012, Navidea has the option to draw a second advance in the principal amount of $3,000,000 (the Second Advance), bearing interest at the same rate and payable on the same terms as the First Advance. The Loan Agreement provides for an interest-only period beginning on December 29, 2011 and expiring on July 1, 2012, provided the interest-only period shall expire on January 1, 2013 upon Navidea’s receipt of FDA approval for Lymphoseek on or before June 30, 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. The outstanding balance of the debt is due December 1, 2014, or June 1, 2015 if the interest-only period is extended following FDA approval of Lymphoseek. In April 2012, we were notified by FDA that our PDUFA date for Lymphoseek has been modified to September 10, 2012, a 90-day extension from the initial PDUFA date of June 10, 2012. Due to the extension of the PDUFA date, we do not expect to receive FDA approval of Lymphoseek by the June 30, 2012 deadline established in the Loan Agreement. Therefore, we may not be able to draw the Second Advance under the current terms, and the interest-only period on the First Advance will expire on July 1, 2012. As such, we have reclassified a portion of the principal, net of related discounts, as a current liability as of March 31, 2012.

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.

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 commercial, research and development expenditures to decline now that the NDA is under review by the FDA; however, we expect expenses related to Lymphoseek to increase in preparation for the commercial launch. We continue to assess timelines and development costs for development of AZD4694 and RIGScan. We are also actively evaluating a number of different product licensing and/or acquisition opportunities, including [^{123}I]-E-IACFT, for which we executed a license option agreement in January 2012. Additional costs related to completing the license and subsequent development expenditures related to [^{123}I]-E-IACFT or some of the other late-stage radiopharmaceutical candidates 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. We believe we have adequate financial resources, when considered with the flexibility of our development plans and anticipated cash flow following the commercialization of Lymphoseek, to permit us to fund some level of pipeline development opportunities. 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 delayed, we may need to revise our financial, operating and development plans.

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. 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 registration statement, 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.

Recent Accounting Developments

In May 2011, the FASB and International Accounting Standards Board (IASB) issued ASU No. 2011-04, *Fair Value Measurement (Topic 820): Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs* (ASU 2011-04). ASU 2011-04 created a uniform framework for applying fair value measurement principles for companies around the world and clarified existing guidance in US GAAP. ASU 2011-04 is effective for interim and annual reporting periods beginning after December 15, 2011 and shall be applied prospectively. The adoption of ASU 2011-04 did not have a material effect on our consolidated financial statements.

In June 2011, the FASB issued ASU No. 2011-05, *Comprehensive Income (Topic 220): Presentation of Comprehensive Income* (ASU 2011-05), as amended by ASU No. 2011-12, *Comprehensive Income (Topic 220): Deferral of the Effective Date for Amendments to the Presentation of Reclassifications of Items Out of Accumulated Other Comprehensive Income in Accounting Standards Update No. 2011-05* (ASU 2011-12). The ASUs increase the prominence of items reported in other comprehensive income (OCI) by eliminating the option to present OCI as part

of the statement of changes in stockholders' equity. The amendments require companies to present all non-owner changes in stockholders' equity, either as one continuous statement or as two separate but consecutive statements. The ASUs do not change the current option for presenting components of OCI gross of the effect of income taxes, provided that such tax effects are presented in the statement in which OCI is presented or disclosed in the notes to the financial statements. Additionally, the standard does not affect the calculation or reporting of earnings per share. The amendments are effective for interim and annual reporting periods beginning after December 15, 2011 and are to be applied retrospectively, with early adoption permitted. The Company adopted the provisions of ASU 2011-05 early which only impacted the presentation on the statement of operations and comprehensive income (loss). ASU 2011-12 also impacts presentation in the financial statements and will have no effect on our financial position or results of operations.

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.

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 March 31, 2012, our $21.9 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 three-month periods ended March 31, 2012 and 2011, we recorded foreign currency transaction losses of $5,000 and $1,000, 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 March 31, 2012, we had approximately $753,000 of derivative liabilities recorded on our balance sheet related to 20,000 of our Series V warrants and 333,333 of our Series GG warrants. A hypothetical 50% increase in our stock price would increase the value of our derivative liabilities by approximately $520,000. A hypothetical 50% decrease in our stock price would decrease the value of our derivative liabilities by approximately $470,000.

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 March 31, 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 March 31, 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 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 New Drug Application (NDA) for Lymphoseek, intended for use in intraoperative lymphatic mapping across a broad range of cancers, is currently under review by the U.S. Food and Drug Administration (FDA). As a part of that review, FDA is reviewing the pre-clinical, clinical and CMC data supporting our application, and, as is also typical of such reviews, is conducting site audits of our facilities and those of the sites where the referenced clinical trials were performed, as well as of contract suppliers and third party vendors being used in the manufacturing and quality assessment processes for Lymphoseek. Such audits, or other inquiries by FDA, could raise questions or issues, requiring us to prepare responses or submit additional data that could delay approval of our NDA. If such questions or issues are raised formally through FDA's issuance of a Complete Response Letter, it would be necessary for us to amend the NDA before it could be approved, a process that would further delay FDA approval. While we continue to believe that the NDA for Lymphoseek is ultimately approvable, it is possible that approval could be delayed as a result of FDA's review process.

Following FDA's acceptance of our Lymphoseek NDA for 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 has been modified to September 10, 2012, a 90-day extension. Further delays in the approval of the NDA could result in delays in our expected revenue from Lymphoseek and increase the use of our cash until any deficiencies cited by FDA are corrected and an amended 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.

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 (AV-45), a first-generation beta-amyloid imaging agent. 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.

We may have difficulty raising additional capital, which could deprive us of necessary resources to pursue our business plans.

We expect to devote significant capital resources to fund research and development, to maintain existing and secure new manufacturing capacity, and to acquire new product candidates. In order to support the initiatives envisioned in our business plan, we may need to raise additional funds through the sale of assets, public or private debt or equity financing, collaborative relationships or other arrangements. Our ability to raise additional financing depends on many factors beyond our control, including the state of capital markets, the market price of our common stock and the development or prospects for development of competitive technology by others. Sufficient additional financing may not be available to us or may be available only on terms that would result in further dilution to the current owners of our common stock.

Our future expenditures on our programs are subject to many uncertainties, including whether our product candidates will be developed or commercialized with a partner or independently. Our future capital requirements will depend on, and could increase significantly as a result of, many factors, including:

- the costs of seeking regulatory approval for our product candidates, including any nonclinical testing or bioequivalence or clinical studies, process development, scale-up and other manufacturing and stability activities, or other work required to achieve such approval, as well as the timing of such activities and approval;
- the extent to which we invest in or acquire new technologies, product candidates, products or businesses and the development requirements with respect to any acquired programs;
- the scope, prioritization and number of development and/or commercialization programs we pursue and the rate of progress and costs with respect to such programs;
- the costs related to developing, acquiring and/or contracting for sales, marketing and distribution capabilities and regulatory compliance capabilities, if we commercialize any of our product candidates for which we obtain regulatory approval without a partner;
- the timing and terms of any collaborative, licensing and other strategic arrangements that we may establish;
- the extent to which we will need to expand our workforce to pursue our business plan, and the costs involved in recruiting, training and incentivizing new employees;
- the effect of competing technological and market developments; and
- the cost involved in establishing, enforcing or defending patent claims and other intellectual property rights.

We believe that we have access to sufficient financial resources with which to fund our operations and those of our subsidiaries for the foreseeable future. However, certain events or actions may shorten the period through which our current operating funds will sustain us, including, without limitation, if we decide to grow our organization in pursuit of development or commercialization activities for our current or newly acquired or developed product candidates, if we incur unexpected expenses, or if FDA approval of Lymphoseek is significantly delayed. We may also acquire new technologies, product candidates and/or products and the cost to acquire, develop and/or commercialize such new technologies, product candidates and/or products may shorten the period through which our current operating funds will sustain us. If our current funds become inadequate, we may not be able to obtain sufficient additional funding for such activities, on satisfactory terms, if at all. If we are unsuccessful in raising additional capital, or the terms of

raising such capital are unacceptable, we may have to modify our business plan and/or significantly curtail our planned development activities, acquisition of new product candidates and other operations.

Due to the extension of the PDUFA date for Lymphoseek to September 10, 2012, we do not expect to 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 may not be available to us under the current terms.

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

None.

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.*

*Filed herewith.

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

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SIGNATURES

In accordance with the requirements of the Exchange Act, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

NAVIDEA BIOPHARMACEUTICALS, INC.
(the Company)
Dated: May 10, 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)