NAVIDEA BIOPHARMACEUTICALS, INC.
Form 10-Q
August 09, 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 June 30, 2012

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

For the transition period from to _____ to _____

Commission File Number: 001-35076

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

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

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

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

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

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

Yes x No ¨

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

Yes x No ¨

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

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

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

Yes ¨ No x

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date: 103,495,382 shares of common stock, par value $.001 per share (as of the close of business on August 1, 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

	June 30, 2012 (unaudited)	December 31, 2011
ASSETS		
Current assets:		
Cash	$16,952,671	$28,644,004
Accounts receivable, net	8,831	15,794
Inventory, net	918,500	821,549
Prepaid expenses and other	813,920	565,174
Total current assets	18,693,922	30,046,521
Property and equipment	1,756,305	1,441,229
Less accumulated depreciation and amortization	1,005,027	977,960
	751,278	463,269
Patents and trademarks	109,612	106,592
Less accumulated amortization	21,171	21,171
	88,441	85,421
Other assets	480,922	598,709
Total assets	$20,014,563	$31,193,920

Continued

Navidea Biopharmaceuticals, Inc. and Subsidiaries,

Consolidated Balance Sheets, continued

	June 30, 2012 (unaudited)	December 31, 2011
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$979,485	$681,754
Accrued liabilities and other	1,486,964	2,097,786
Note payable to investor, net of discount of $242,922	2,341,151	—
Derivative liabilities, current	793,418	568,930
Total current liabilities	5,601,018	3,348,470
Note payable to investor, net of discounts of $183,536 and $543,612, respectively	4,232,391	6,456,388
Other liabilities	252,247	257,315
Total liabilities	10,085,656	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 June 30, 2012 and December 31, 2011	10	10
Common stock; $.001 par value; 200,000,000 shares authorized; 96,809,622 and 95,398,961 shares issued and outstanding at June 30, 2012 and December 31, 2011, respectively	96,810	95,399
Additional paid-in capital	268,063,288	266,393,645
Accumulated deficit	(258,231,201)	(245,357,307)
Total stockholders' equity	9,928,907	21,131,747
Total liabilities and stockholders' equity	$20,014,563	$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 June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
Revenue	$60,000	$6,135	$71,931	$342,097
Operating expenses:				
Research and development	2,476,113	1,866,252	6,419,827	4,301,851
Selling, general and administrative	2,970,837	1,727,145	5,545,467	4,628,853
Total operating expenses	5,446,950	3,593,397	11,965,294	8,930,704
Loss from operations	(5,386,950)	(3,587,262)	(11,893,363)	(8,588,607)
Other income (expense):				
Interest income	8,170	2,984	17,903	6,503
Interest expense	(321,405)	(1,058)	(615,076)	(2,665)
Change in derivative liabilities	(92,805)	(10,352)	(276,889)	(964,141)
Other	(41,832)	(386)	(56,469)	(1,097)
Total other expense, net	(447,872)	(8,812)	(930,531)	(961,400)
Loss before income taxes	(5,834,822)	(3,596,074)	(12,823,894)	(9,550,007)
Benefit from income tax	—	478,444	—	999,257
Loss from continuing operations	(5,834,822)	(3,117,630)	(12,823,894)	(8,550,750)
Discontinued operations – Income from operations, net of tax effect	—	928,740	—	1,939,731
Net loss and comprehensive loss	(5,834,822)	(2,188,890)	(12,823,894)	(6,611,019)
Preferred stock dividends	(25,000)	(25,000)	(50,000)	(50,000)
Net loss and comprehensive loss attributable to common stockholders	$(5,859,822)	$(2,213,890)	$(12,873,894)	$(6,661,019)
Loss per common share (basic and diluted):				
Continuing operations	$(0.06)	$(0.03)	$(0.14)	$(0.10)
Discontinued operations	$—	$0.01	$—	$0.02
Attributable to common stockholders	$(0.06)	$(0.02)	$(0.14)	$(0.08)

Weighted average shares outstanding:				
Basic and diluted	94,664,659	89,660,089	94,368,690	87,549,776

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	—	—	435,000	435	—	—	435
Cancelled restricted stock	—	—	(4,500)	(5)	5	—	—
Issued stock upon exercise of stock options, net	—	—	980,271	981	527,774	—	528,755
Cancelled stock upon repurchase from executives	—	—	(37,500)	(37)	(100,838)	—	(100,875)
Issued stock to 401(k) plan	—	—	17,390	17	50,255	—	50,272
Issued stock upon exercise of warrants, net	—	—	20,000	20	58,581	—	58,601
Stock compensation expense	—	—	—	—	1,133,866	—	1,133,866
Preferred stock dividends	—	—	—	—	—	(50,000)	(50,000)
Net loss	—	—	—	—	—	(12,823,894)	(12,823,894)
Balance, June 30, 2012	10,083	$ 10	96,809,622	$96,810	$268,063,288	$(258,231,201)	$9,928,907

See accompanying notes to consolidated financial statements.

Navidea Biopharmaceuticals, Inc. and Subsidiaries

Consolidated Statements of Cash Flows

(unaudited)

	Six Months Ended June 30,	
	2012	2011
Cash flows from operating activities:		
Net loss	$(12,823,894)	$(6,611,019)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	87,091	110,023
Loss on disposal and abandonment of assets	—	18,503
Amortization of debt discount and debt offering costs	260,415	—
Stock compensation expense	1,133,866	1,284,095
Change in derivative liabilities	276,889	964,141
Issuance of common stock to 401(k) plan	50,272	48,289
Changes in operating assets and liabilities:		
Accounts receivable	16,463	11,787
Inventory	(96,951)	(206,525)
Prepaid expenses and other assets	(283,720)	134,085
Accounts payable	297,731	56,331
Accrued liabilities and other liabilities	(459,264)	1,355,507
Deferred revenue	—	249,674
Net cash used in operating activities	(11,541,102)	(2,585,109)
Cash flows from investing activities:		
Purchases of equipment	(375,100)	(79,749)
Proceeds from sales of equipment	—	1,000
Patent and trademark costs	(3,020)	(4,660)
Net cash used in investing activities	(378,120)	(83,409)
Cash flows from financing activities:		
Proceeds from issuance of common stock	544,155	6,306,528
Payment for common stock repurchased from executives	(100,875)	—
Payment of tax withholdings related to stock-based compensation	(8,765)	(2,404,638)
Payment of preferred stock dividends	(50,000)	(50,000)
Payment of debt issuance costs	(153,949)	—
Payment of notes payable	—	(53,339)
Payments under capital leases	(2,677)	(6,144)
Net cash provided by financing activities	227,889	3,792,407
Net (decrease) increase in cash	(11,691,333)	1,123,889

Cash, beginning of period	28,644,004	6,420,506
Cash, end of period	$16,952,671	$7,544,395

See accompanying notes to consolidated financial statements.

1. Summary of Significant Accounting Policies

a. **Basis of Presentation:** The information presented as of June 30, 2012, and for the three-month and six-month periods ended June 30, 2012 and June 30, 2011, is unaudited, but includes all adjustments (which consist only of normal recurring adjustments) that the management of Navidea Biopharmaceuticals, Inc. (Navidea, the Company, or we) believes to be necessary for the fair presentation of results for the periods presented. Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America have been condensed or omitted pursuant to the rules and regulations of the U.S. Securities and Exchange Commission. The balances as of June 30, 2012, and the results for the interim periods, are not necessarily indicative of results to be expected for the year. The consolidated financial statements should be read in conjunction with Navidea's audited consolidated financial statements for the year ended December 31, 2011, which were included as part of our Annual Report on Form 10-K.

Our consolidated financial statements include the accounts of Navidea, our wholly owned subsidiaries, Navidea Biopharmaceuticals Limited and Cardiosonix Ltd. (Cardiosonix), and our majority-owned subsidiary, Cira Biosciences, Inc. (Cira Bio). All significant inter-company accounts were eliminated in consolidation.

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

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

Our consolidated balance 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 June 30, 2012 and December 31, 2011 is presented as the face amount of the note less unamortized discounts. At June 30, 2012, the fair value of the note payable to investor is approximately $7.0 million, which approximates face value. See Note 8.

(3) Derivative liabilities: Derivative liabilities are related to certain outstanding warrants which are recorded at fair value. The assumptions used to calculate fair value as of June 30, 2012 and December 31, 2011 include volatility, risk-free rate and expected dividends. In addition, we considered non-performance risk and determined that such risk is minimal. Unrealized gains and losses on the derivatives are classified in other expenses as a change in derivative liabilities in the statements of operations. See Note 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, we reclassified revenues and expenses related to the GDS Business and our Cardiosonix subsidiary to discontinued operations. The following amounts have been segregated from continuing operations and included in discontinued operations in the consolidated statements of operations:

	Three Months Ended June 30, 2011	Six Months Ended June 30, 2011
Net sales	$ 3,201,095	$ 5,736,934
Cost of goods sold	1,004,336	1,762,949

Gross profit	2,196,759	3,973,985
Operating expenses:		
Research and development	102,133	278,219
Selling, general and administrative	687,355	756,557
Total operating expenses	789,488	1,034,776
Other expense, net	(87)	(221)
Income taxes	(478,444)	(999,257)
Income from discontinued operations	$ 928,740	$ 1,939,731

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 June 30, 2012

Description	Quoted Prices in Active Markets for Identical Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Balance as of June 30, 2012
Liabilities:				
Derivative liabilities related to warrants, current	$ —	$ 793,418	$ —	$ 793,418

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 and six-month periods ended June 30, 2012 and 2011. There were no transfers in or out of our Level 2 liabilities during the three-month or six-month periods ended June 30, 2012. A total of $1,978,818 of our Level 2 liabilities were reclassified to equity related to modifying certain outstanding warrants to remove the language that had previously required them to be classified as derivative liabilities during the six-month period ended June 30, 2011. See Note 9.

4. Stock-Based Compensation

At June 30, 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 June 30, 2012 and 2011, our total stock-based compensation expense was approximately $716,000 and $279,000, respectively. For the six-month periods ended June 30, 2012 and 2011, our total stock-based compensation expense was approximately $1.1 million and $1.3 million, respectively. Stock-based compensation expense for the first six months of 2011 included approximately $718,000 of expense related to the separation of our former President and CEO. (See Note 7.) We have not recorded any income tax benefit related to stock-based compensation in any of the three-month or six-month periods ended June 30, 2012 and 2011.

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

	Six Months Ended June 30, 2012			
	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value
Outstanding at beginning of period	3,315,000	$ 1.02		
Granted	1,039,763	3.20		
Exercised	(987,001)	0.55		
Forfeited	(10,499)	2.00		
Expired	—	—		
Outstanding at end of period	3,357,263	$ 1.83	6.5 years	$6,475,645
Exercisable at end of period	1,795,134	$ 0.93	4.2 years	$5,034,132

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

	Six Months Ended June 30, 2012	
	Number of Shares	Weighted Average Grant-Date Fair Value
Unvested at beginning of period	1,556,000	$ 2.48
Granted	385,000	3.16
Vested	—	—
Forfeited	—	—
Expired	—	—
Unvested at end of period	1,941,000	$ 2.62

As of June 30, 2012, there was approximately $2.6 million of total unrecognized compensation expense related to unvested stock-based awards, which we expect to recognize over remaining weighted average vesting terms of 1.9 years.

5. Earnings (Loss) Per Share

Basic earnings (loss) per share is calculated by dividing net income (loss) attributable to common stockholders by the weighted-average number of common shares and, except for periods with a loss from operations, participating securities outstanding during the period. Diluted earnings (loss) per share reflects additional common shares that would have been outstanding if dilutive potential common shares had been issued. Potential common shares that may be issued by the Company include convertible securities, options and warrants.

The following table sets forth the reconciliation of the weighted average number of common shares outstanding to those used to compute basic and diluted earnings (loss) per share for the three-month and six-month periods ended June 30, 2012 and 2011:

	Basic and Diluted Earnings Per Share			
	Three Months Ended June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
Outstanding shares	96,809,622	94,537,936	96,809,622	94,537,936
Effect of weighting changes in outstanding shares	(203,963)	(3,191,347)	(499,932)	(5,301,660)
Unvested restricted stock	(1,941,000)	(1,686,500)	(1,941,000)	(1,686,500)
Adjusted shares	94,664,659	89,660,089	94,368,690	87,549,776

Earnings (loss) per common share for the three-month and six-month periods ended June 30, 2012 and 2011 excludes the effects of 55.2 million and 54.7 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, 1,941,000 and 1,686,500 shares of unvested restricted stock were excluded in determining basic and diluted loss per share for the three-month and six-month periods ended June 30, 2012 and 2011, respectively, because such inclusion would be anti-dilutive.

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6. Inventory, net

All components of inventory are valued at the lower of cost (first-in, first-out) or market. We adjust inventory to market value when the net realizable value is lower than the carrying cost of the inventory. Market value is determined based on estimated sales activity and margins. From time to time, we capitalize certain inventory costs associated with our Lymphoseek® product prior to regulatory approval and product launch based on management's judgment of probable future commercial use and net realizable value of the inventory. We could be required to permanently write down previously capitalized costs related to pre-approval or pre-launch inventory upon a change in such judgment, due to a denial or delay of approval by regulatory bodies, a delay in commercialization, slower than expected sales, or other potential factors. Conversely, our gross margins may be favorably impacted if some or all of the inventory previously expensed becomes available and is used for commercial sale. During the six-month periods ended June 30, 2012 and 2011, we capitalized $525,000 and $213,000, respectively, of inventory costs associated with our Lymphoseek product. During the three-month periods ended June 30, 2012 and 2011, we did not capitalize any such costs. During the six-month period ended June 30, 2012, we wrote off $89,000 of previously capitalized Lymphoseek inventory due to the consumption of the Lymphoseek material in previously unanticipated product development activities. During the three-month periods ended June 30, 2012 and 2011, and the six-month period ended June 30, 2011, we did not write off any such costs.

The components of net inventory as of June 30, 2012 and December 31, 2011, net of reserves of $339,000 and $0, respectively, are as follows:

	June 30, 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 six-month period ended June 30, 2012, we recorded an obsolescence reserve for $339,000 of Lymphoseek inventory due to changes in our projections of the probability of future commercial use for the specific lots previously capitalized.

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 June 30, 2012 and December 31, 2011, including employer payroll tax obligations, related to the provisions of Mr. Bupp's separation agreement:

	June 30, 2012 (unaudited)	December 31, 2011
Separation	$ —	$ 180,074
Pro-rated 2011 bonus	—	60,870
Estimated continuing healthcare coverage	31,771	61,875
	$ 31,771	$ 302,819

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8. Convertible Securities

In May 2011, Platinum-Montaur Life Sciences, LLC (Montaur) converted 917 shares of their Series B Convertible Preferred Stock (the Series B) into 2,998,590 shares of our common stock under the terms of the Series B. As of June 30, 2012, there are 9,083 shares of Series B outstanding which are convertible into 29,701,410 shares of our common stock.

In December 2011, we executed a Loan and Security Agreement (the Loan Agreement) with Hercules Technology II, L.P. (Hercules), providing for a maximum borrowing of $10 million by the Company in two advances. Pursuant to the Loan Agreement, we issued Hercules: (1) a Secured Term Promissory Note in the principal amount of $7,000,000 (the First Advance), bearing interest at the greater of either (a) the U.S. Prime Rate as reported in The Wall Street Journal plus 6.75%, or (b) 10.0% (effective interest rate at June 30, 2012 was 10.0%), and (2) a Series GG Warrant to purchase 333,333 shares of our common stock at an exercise price of $2.10 per share, expiring in December 2016 (the Series GG Warrant). Additionally, pursuant to the terms of the Loan Agreement, if the U.S. Food and Drug Administration (FDA) approval of Lymphoseek had occurred on or before June 30, 2012, Navidea would have had 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. 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. Navidea has the option to pay up to $1.5 million of the principal amount of the debt in stock at a fixed conversion price of $2.77, subject to certain conditions. In addition, Hercules has the option to elect payment for up to another $1.5 million of the principal amount of the debt by conversion at a fixed conversion price of $2.77.

In 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 did not receive FDA approval of Lymphoseek by the June 30, 2012 deadline established in the Loan Agreement. Therefore, we were not able to draw the Second Advance under the current terms, and the interest-only period on the First Advance expired on July 1, 2012. As such, we have reclassified a portion of the principal, net of related discounts, as a current liability as of June 30, 2012.

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 June 30, 2012, we were in compliance with all such covenants.

In accordance with current accounting standards, Hercules’ option to convert up to $1.5 million of the debt into stock was evaluated and determined to be a beneficial conversion feature. The beneficial conversion feature of $24,888 was

recorded as a discount on the First Advance based on the market price of the Company's stock on the date of the Loan Agreement. In addition, the Series GG Warrant was accounted for as a liability at origination due to the existence of certain provisions in the instrument which will remain in effect for the first 365 days the warrant is outstanding.

During the three-month and six-month periods ended June 30, 2012, we recorded interest expense of $144,000 and $260,000, respectively, related to amortization of the debt discounts and deferred financing costs related to our convertible note.

9. Derivative Instruments

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

During the first six months of 2012, an outside investor exercised 20,000 Series V warrants, resulting in reclassification of $52,000 in derivative liabilities related to those warrants to additional paid-in capital. During the first six months of 2011, certain outside investors exercised 1,578,948 Series CC warrants, 1,194,211 Series DD warrants, 810,000 Series V warrants, and 60,000 Series Z warrants, resulting in reclassification of $1.4 million in derivative liabilities related to those warrants to additional paid-in capital.

The net effect of marking the Company's derivative liabilities to market during the three-month periods ended June 30, 2012 and 2011 resulted in net increases in the estimated fair values of the derivative liabilities of approximately $93,000 and $10,000, respectively, which were recorded as non-cash expense. The net effect of marking the Company's derivative liabilities to market during the six-month periods ended June 30, 2012 and 2011 resulted in net increases in the estimated fair values of the derivative liabilities of approximately $277,000 and $964,000, respectively, which were also recorded as non-cash expense. The total estimated fair value of the remaining derivative liabilities was $793,000 and $569,000 as of June 30, 2012 and December 31, 2011, respectively.

10. Stock Warrants

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

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

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 June 30, 2012 and December 31, 2011. An estimated provision for income taxes of $478,000 and $999,000 related to income from discontinued operations was offset by the estimated tax benefit related to the loss from continuing operations during the three-month and six-month periods ended June 30, 2011, respectively.

12. Supplemental Disclosure for Statements of Cash Flows

During the six-month periods ended June 30, 2012 and 2011, we paid interest aggregating $302,000 and $3,000, respectively. During the six-month periods ended June 30, 2012 and 2011, we issued 17,390 and 30,348 shares of our common stock, respectively, as matching contributions to our 401(k) plan. During the six-month period ended June 30, 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.

13. Subsequent Events

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

b. **Preferred Stock Conversion:** Also in July 2012, Montaur converted 3,063 shares of their Series B Convertible Preferred Stock into 10,016,010 shares of our common stock under the terms of the Series B Convertible Preferred Stock.

c. **License Agreement:** On July 31, 2012, we entered into an agreement with Alseres Pharmaceuticals, Inc. (Alseres) to license [^{123}I]-E-IACFT Injection (CFT), an Iodine-123 radiolabeled imaging agent being developed as an aid in the diagnosis of Parkinson's disease and other movement disorders, with a potential use as a diagnostic aid in dementia. Under the terms of the license agreement, Alseres granted Navidea an exclusive, worldwide sub-license to research, develop and commercialize CFT. The final terms of the agreement require Navidea to make a one-time sub-license execution payment to Alseres equal to (i) $175,000 in cash and (ii) 300,000 shares of our common stock.

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

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

Forward-Looking Statements

This report contains forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends affecting the financial condition of our business. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including, among other things:

- general economic and business conditions, both nationally and in our markets;
- our history of losses, negative net worth and uncertainty of future profitability;
- our ability to successfully complete research and further development of our drug candidates;
- the timing, cost and uncertainty of obtaining regulatory approvals of our drug candidates;
- our ability to successfully commercialize our drug candidates;
- our expectations and estimates concerning future financial performance, financing plans and the impact of competition;
- our ability to raise capital sufficient to fund our development and commercialization programs;
- our ability to implement our growth strategy;
- anticipated trends in our business;
- advances in technologies; and
- other risk factors set forth in this report and detailed in our most recent Annual Report on Form 10-K and other SEC filings.

In addition, in this report, we use words such as "anticipate," "believe," "plan," "expect," "future," "intend," and similar expressions to identify forward-looking statements.

We undertake no obligation to update publicly or revise any forward-looking statements, whether as a result of new information, future events or otherwise after the date of this report. In light of these risks and uncertainties, the forward-looking events and circumstances discussed in this report may not occur and actual results could differ materially from those anticipated or implied in the forward-looking statements.

The Company

Navidea Biopharmaceuticals, Inc. (Navidea, the Company, or we), a Delaware corporation, is a biopharmaceutical company focused on the development and commercialization of precision diagnostics and radiopharmaceutical agents. We are currently developing four radiopharmaceutical agent platforms. The first, Lymphoseek® (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. The fourth, E-IACFT (CFT), is an Iodine-123 radiolabeled imaging agent being developed as an aid in the diagnosis of Parkinson's disease and other movement disorders, with potential use as a diagnostic aid in dementia. All of these drug products are still in development and must be cleared for marketing by the appropriate regulatory authorities before they can be sold in any markets.

Product Line Overview

We believe that the future prospects for Navidea continue to improve as we make progress in executing our strategic vision to become a leader in precision diagnostics. Our primary development efforts over the last few years have been focused on the development of our Lymphoseek product candidate. We expect our overall research and development expenditures to continue to be significantly higher during 2012 as compared to 2011 due to the expansion of our clinical, regulatory, and business development staff and efforts that support the commercialization of Lymphoseek, further development of AZD4694, RIGScan and CFT, and sourcing and development of additional pipeline product candidates. The level to which the expenditures rise will depend on the extent to which we are able to execute on these strategic initiatives.

Lymphoseek

The initial pre-clinical evaluations of Lymphoseek were completed by the University of California, San Diego (UCSD) in 2001. Since that time, Navidea, in cooperation with UCSD, has completed or initiated five Phase 1 clinical trials, one multi-center Phase 2 trial and three multi-center Phase 3 trials involving Lymphoseek. Two comprehensive Phase 3 studies 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 G. Komen Breast Cancer Research Foundation have been published in leading medical journals including Journal of Nuclear Medicine and Annals of Surgical Oncology.

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

We began a multi-center Phase 2 clinical study of Lymphoseek 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, the results of which 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 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.

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.

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 by 90 days to September 10, 2012 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. 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 provide evidence of Lymphoseek performance in a third cancer type and 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 during the second half of 2012 that would enable an interim analysis of the trial data.

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.

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 and specificity.

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 the second half of 2012, primarily to expand the safety database for the compound. We recently received approval from a centralized institutional review board for the Phase 2 protocol. We also expect to initiate a Phase 3 trial in early 2013 to support registration in the U.S. and the EU.

RIGScan

Radio-immunoguided surgery (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. The antibody is administered prior to surgery and is 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.

Our RIGScan technology is a radiolabeled murine monoclonal antibody (CC49 MAb, Minretumomab) that serves as the biologic targeting agent for intraoperative detection of occult or metastatic cancer. 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.

In 1996, Navidea submitted applications to EMA and FDA for marketing approval of RIGScan for the detection of metastatic colorectal cancer based primarily on results of a single Phase 3 clinical trial, NEO2-14, 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.

To resume RIGScan development, we filed a new IND request with FDA 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 to use a humanized version of the RIGScan antibody. With this collective guidance, we have transitioned from a murine antibody to a humanized antibody. We have since focused on manufacturing the humanized antibody with the aim of completing the necessary manufacturing steps to support the start of clinical development; however, as management continues to assess the scope and required resources for the RIGScan program, particularly in light of other development opportunities such as for AZD4694, CFT, or other agents, the timing and scope of our development and commercialization plan for RIGScan may be affected.

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

E-IACFT

In January 2012, we executed an option agreement with Alseres Pharmaceuticals, Inc. (Alseres) to license CFT. 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. In order to perform thorough due diligence, Navidea extended the option period from June 30, 2012, to July 31, 2012. On July 31, 2012, we entered into an agreement to license CFT from Alseres. Under the terms of the license agreement, Alseres granted Navidea an exclusive, worldwide sub-license to research, develop and commercialize CFT. The final terms of the agreement call for Navidea to make a one-time sub-license execution payment to Alseres equal to (i) $175,000 in cash and (ii) 300,000 shares of our common stock. The license agreement also provides for contingent milestone payments of up to $2.9 million, $2.5 million of which will principally occur at the time of product registration or upon commercial sales, and the issuance of up to an additional 1.15 million shares of Navidea common stock, 950,000 shares of which are issuable at the time of product registration or upon commercial sales. In addition, the license terms anticipate royalties on annual net sales of the approved product which are consistent with industry-standard terms and certain license extension fees, payable in cash

and shares of common stock, in the event certain diligence milestones are not met.

CFT 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.

CFT has been administered to over 600 subjects to date. Results from clinical trials have demonstrated that CFT 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, CFT may also be useful in the diagnosis of Dementia with Lewy Bodies (DLB), one of the most common forms of dementia after AD.

Outlook

We spent approximately $6.4 million and $4.3 million on research and development activities during the six-month periods ended June 30, 2012 and 2011, respectively. Of the total amounts we spent on research and development during those periods, excluding costs related to our internal research and development headcount and our general and administrative staff which we do not currently allocate among the various development programs that we have underway, we incurred charges by program as follows:

	Six Months Ended June 30,	
Development Program	2012	2011
Lymphoseek	$2,668,530	$2,194,617
AZD4694	397,991	—
RIGScan	230,648	575,269
[^{123}I]-E-IACFT	659,932 (a)	—

(a) Amount includes a $500,000 license option fee paid in January 2012.

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

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

During 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.

Depending on the timing and outcome of the FDA regulatory review cycle, which precedes certain required pre-launch activities, 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. We also cannot assure you that Lymphoseek will achieve regulatory approval in the U.S., the EU or any market, or if approved, that it will achieve market acceptance.

We also expect to incur significant expenses 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 cannot assure you that further clinical trials for this product will be successful, that the agent will ultimately achieve regulatory approval, or if approved, the extent to which it will achieve market acceptance.

We are in the process of evaluating the business, manufacturing, development and regulatory pathways forward with respect to RIGScan. 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 the recent license for CFT, and as such 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 RIGScan product would likely be a minimum of five years before we receive any significant product-related royalties or revenues. We cannot assure you that we will be able to complete satisfactory development arrangements or obtain incremental financing to fund development of the RIGS technology and cannot guarantee that such arrangements could be obtained on a timely basis on terms acceptable to us, or at all. We also cannot assure you that further clinical development will be successful, that FDA or EMA will clear RIGScan for marketing, or that it will be successfully introduced or achieve market acceptance.

We also plan to finalize a regulatory approach and draft of the clinical development plan for CFT by the end of 2012. The timing and extent of expected expenditures related to CFT will be better known following the completion of such plan.

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

Discontinued Operations

From our inception through August 2011, we developed and marketed a line of medical devices, the neoprobe® GDS gamma detection systems (the GDS Business). However, following an analysis of our strategic goals and objectives, our Board of Directors authorized, and our stockholders approved, the sale of the GDS Business as well as the disposal of the related extended warranty contracts to Devicor Medical Products, Inc. for a net purchase price of $30.1 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 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.

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 in the next 12 months. During the six-month period ended June 30, 2012, Navidea recognized an additional $12,000 of miscellaneous grant revenue. Also during the six-month period ended June 30, 2012, Navidea recognized revenue of $60,000 related to reimbursement of certain Lymphoseek commercialization activities, for which the Company had principal responsibility, by our distribution partner, Cardinal Health, Inc.

Three Months Ended June 30, 2012 and 2011

Revenue. Revenue of $60,000 during the second quarter of 2012 was related to reimbursement of certain Lymphoseek commercialization activities by our distribution partner, Cardinal Health, Inc. Revenue of $6,000 during the second quarter of 2011 was related to the Ohio Third Frontier grant to support Lymphoseek development.

Research and Development Expenses. Research and development expenses increased $610,000, or 33%, to $2.5 million during the second quarter of 2012 from $1.9 million during the same period in 2011. The increase was primarily due to net increases in drug project expenses related to (i) increased AZD4694 development costs including project management and clinical trial development fees of $132,000, consulting costs of $76,000, and manufacturing-related costs of $31,000, (ii) a net increase in Lymphoseek development costs including increased manufacturing-related costs of $323,000 and regulatory consulting costs of $120,000, offset by decreased clinical activity costs of $264,000, (iii) consulting costs related to potential pipeline products of $113,000, and (iv) consulting costs for due diligence work related to the in-licensing of CFT of $77,000; offset by (v) a net decrease in RIGScan development costs including decreased manufacturing-related costs of $248,000 and decreased consulting fees of $59,000. The net increase in research and development expenses was also due to increased compensation of $174,000 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, travel and general office expenses.

Selling, General and Administrative Expenses. Selling, general and administrative expenses increased $1.2 million, or 72%, to $3.0 million during the second quarter of 2012 from $1.7 million during the same period in 2011. The net increase was primarily due to increased marketing costs related to the commercial launch of Lymphoseek of $846,000, increased compensation costs of $421,000 related to increased headcount and incentive-based compensation, and increased travel, insurance and other expenses to support the increased headcount of $225,000, offset by decreased legal fees primarily related to certain investor matters in the second quarter of 2011 of $167,000.

Other Income (Expenses). Other expense, net, was $448,000 during the second quarter of 2012 as compared to $9,000 during the same period in 2011. Interest expense increased $320,000 to $321,000 during the second quarter of 2012 from $1,000 for the same period in 2011, due to the note payable we entered into in December 2011. Of this interest expense, $144,000 in the second quarter of 2012 was non-cash in nature related to the amortization of debt issuance costs and debt discounts resulting from the warrants issued and conversion features embedded in the note. During the second quarter of 2012 and 2011, we recorded charges of $93,000 and $10,000, respectively, related to the increases in derivative liabilities resulting from the requirement to mark our derivative liabilities to market.

Income Taxes. An estimated provision for income taxes of $478,000 related to income from discontinued operations was offset by the estimated tax benefit related to the loss from continuing operations during the second quarter of 2011.

Income from Discontinued Operations. The income from discontinued operations was $929,000, net of $478,000 in estimated taxes, during the second quarter of 2011 and was primarily related to the operation of our GDS Business, which was sold to Devicor in August 2011.

Six Months Ended June 30, 2012 and 2011

Revenue. Revenue of $60,000 during the first half of 2012 was related to reimbursement of certain Lymphoseek commercialization activities by our distribution partner, Cardinal Health, Inc. Revenue of $336,000 during the first half of 2011 was related to the Ohio Third Frontier grant to support Lymphoseek development. Additional revenue of $12,000 and $6,000 during the first half of 2012 and 2011, respectively, was related to Ohio Third Frontier grants to support student internships.

Research and Development Expenses. Research and development expenses increased $2.1 million, or 49%, to $6.4 million during the first half of 2012 from $4.3 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 $160,000 of due diligence activities related to CFT, (ii) a net increase in Lymphoseek development costs including increased manufacturing-related costs of $523,000, the reserve for obsolescence related to previously capitalized Lymphoseek inventory of $339,000, regulatory consulting costs of $325,000, and consulting costs related to preparation for a potential FDA Advisory Committee meeting of $319,000, offset by decreased clinical activity costs of $1.0 million, (iii) increased AZD4694 development costs including project management and clinical trial development fees of $215,000, consulting costs of $124,000, and manufacturing-related costs of $50,000, and (iv) consulting costs related to potential pipeline products of $232,000; offset by (v) a decrease in RIGScan development costs including decreased consulting fees of $234,000 and decreased manufacturing-related costs of $79,000. The net increase in research and development expenses was also due to increased compensation of $361,000 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, travel, recruiting and general office expenses.

Selling, General and Administrative Expenses. Selling, general and administrative expenses increased $917,000, or 20%, to $5.5 million during the first half of 2012 from $4.6 million during the same period in 2011. The net increase was primarily due to our formation of a marketing and business development team during the second half of 2011, contributing to increased marketing costs related to the pending commercial launch of Lymphoseek of $1.5 million, increased compensation costs of $1.0 million related to increased headcount and incentive-based compensation, and increased travel, insurance, recruiting and other expenses to support the increased headcount of $390,000, offset by separation costs of $1.9 million related to our former President and CEO which were recorded during the first half of 2011 and decreased legal fees of $100,000, primarily related to certain investor matters in the first half of 2011.

Other Income (Expenses). Other expense, net, was $931,000 during the first half of 2012 as compared to $961,000 during the same period in 2011. Interest expense increased $612,000 to $615,000 during the first half of 2012 from $3,000 for the same period in 2011, due to the note payable we entered into in December 2011. Of this interest expense, $260,000 in the first half of 2012 was non-cash in nature related to the amortization of debt issuance costs and debt discounts resulting from the warrants issued and conversion features embedded in the note. During the first half of 2012 and 2011, we recorded charges of $277,000 and $964,000, respectively, related to the increases in derivative liabilities resulting from the requirement to mark our derivative liabilities to market.

Income Taxes. An estimated provision for income taxes of $999,000 related to income from discontinued operations was offset by the estimated tax benefit related to the loss from continuing operations during the first half of 2011.

Income from Discontinued Operations. The income from discontinued operations was $1.9 million, net of $999,000 in estimated taxes, during the first half of 2011 and was primarily related to the operation of our GDS Business, which was sold to Devicor in August 2011.

Liquidity and Capital Resources

Cash balances decreased to $17.0 million at June 30, 2012 from $28.6 million at December 31, 2011. The net decrease was primarily due to cash used to fund our operations, mainly for research and development activities. The current ratio decreased to 3.3:1 at Jun 30, 2012 from 9.0:1 at December 31, 2011.

Operating Activities. Cash used in operations increased $8.9 million to $11.5 million during the first half of 2012 compared to $2.6 million during the same period in 2011.

Inventory levels increased to $919,000 at June 30, 2012 from $822,000 at December 31, 2011. An increase in pharmaceutical materials was related to the 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 $979,000 at June 30, 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 $1.5 million at June 30, 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 President and CEO, David Bupp, during the first half 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 $378,000 during the first half of 2012 compared to using $83,000 during the same period in 2011. Capital expenditures of $375,000 during the first half of 2012 were primarily for equipment to be used in the production of AZD4694 and Lymphoseek, computers, software, and furniture and fixtures for the new branch office in Andover, MA. Capital expenditures of $80,000 during the first half of 2011 were primarily for computers, software, and equipment to be used in the production of Lymphoseek and gamma detection devices. We expect our overall capital expenditures for the remainder of 2012 will be higher than in 2011. Payments for patent and trademark costs were $3,000 and $5,000 during the first half of 2012 and 2011, respectively.

Financing Activities. Financing activities provided $228,000 during the first half of 2012 compared to $3.8 million provided during the same period in 2011. The $228,000 provided by financing activities in the first half of 2012 consisted primarily of net proceeds from the issuance of common stock of $544,000, offset by payments of debt issuance costs of $154,000, payment for common stock repurchased from executives of $101,000, payment of preferred stock dividends of $50,000, payment of tax withholdings related to stock-based compensation of $9,000, and payments of capital leases of $3,000. The $3.8 million provided by financing activities in the first half of 2011 consisted primarily of proceeds from the issuance of common stock of $6.3 million, offset by payments of tax withholdings related to stock-based compensation of $2.4 million, including costs related to the net exercise of stock options by our former President and CEO of $2.1 million, and payments of notes payable of $53,000, preferred stock dividends of $50,000, and capital leases of $6,000.

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 June 30, 2012 and December 31, 2011 was 10.0%), and (2) a Series GG Warrant to purchase 333,333 shares of our common stock at an exercise price of $2.10 per share, expiring in December 2016 (the Series GG Warrant). The Series GG Warrant was accounted for as a derivative 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 had occurred on or before June 30, 2012, Navidea would have had 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. 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. 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 did not receive FDA approval of Lymphoseek by the June 30, 2012 deadline established in the Loan Agreement. Therefore, we were not able to draw the Second Advance under the current terms, and the interest-only period on the First Advance expired on July 1, 2012. As such, we have reclassified a portion of the principal, net of related discounts, as a current liability as of June 30, 2012.

In July 2012 and May 2011, Platinum-Montaur Life Sciences, LLC (Montaur) converted 3,063 and 917 shares, respectively, of their Series B Convertible Preferred Stock (the Series B) into 10,016,010 and 2,998,590 shares, respectively, of our common stock under the terms of the Series B. As of June 30, 2012, there were 9,083 shares of Series B outstanding which are convertible into 29,701,410 shares of our common stock.

Our most significant near-term development priority is to continue our regulatory and pre-commercialization activities related to Lymphoseek. We continue to expect Lymphoseek-related research and development expenditures to decline now that the NDA is under review by FDA; however, we expect marketing expenses related to Lymphoseek to increase in preparation for the commercial launch. We continue to assess timelines and development costs for development of AZD4694, RIGScan and CFT. We are also actively evaluating a number of different product licensing and/or acquisition opportunities. Costs related to in-licensing, acquiring and developing other late-stage radiopharmaceutical candidates that we are evaluating, coupled with development costs related to our existing product candidates, may result in the use of a material portion of our available funds. 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.

Our future liquidity and capital requirements will depend on a number of factors, including our ability to complete the development and commercialization of new products, our ability to achieve market acceptance of our products, our ability to monetize our investment in non-core technologies, our ability to obtain milestone or development funds from potential development and distribution partners, regulatory actions by FDA and international regulatory bodies, the ability to procure additional pipeline development opportunities and required financial resources, and intellectual property protection.

We filed a shelf registration statement in 2011 to provide us with future funding alternatives and flexibility as we execute on our plans to achieve our product development and commercialization goals, as well as evaluating and acting on opportunities to expand our product pipeline. In July 2012, we entered into an agreement with Montaur to provide us with a credit facility of up to $50 million. Under the terms of the agreement, Montaur committed to extend up to $15 million in debt, which is available immediately, to the Company at a prime-based interest rate currently at approximately 10% per annum. Montaur has committed an additional $20 million upon FDA approval of Lymphoseek on consistent terms, with another $15 million potentially available on terms to be negotiated. No conversion features or warrants are associated with the facility.

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 or the credit facility, we will continue our efforts to maintain a strong balance sheet. Even if we decide to attempt to raise additional capital, we cannot assure you that we will be successful in doing so on terms acceptable to the Company, or at all. We also cannot assure you that we will be able to gain access and/or be able to execute on securing new development opportunities, successfully obtain

regulatory approval for and commercialize new products, achieve significant product revenues from our products, or achieve or sustain profitability in the future.

Critical Accounting Policies

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

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

Use of Estimates. The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. We base these estimates and assumptions upon historical experience and existing, known circumstances. Actual results could differ from those estimates. Specifically, management may make significant estimates in the following areas:

- *Stock-Based Compensation*. Stock-based payments to employees and directors, including grants of stock options and restricted stock, are recognized in the statements of operations based on their estimated fair values on the date of grant. The fair value of each option award is estimated on the date of grant using the Black-Scholes option pricing model to value share-based payments. Compensation cost arising from stock-based awards is recognized as expense using the straight-line method over the vesting period.

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

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

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Item 3. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk. As of June 30, 2012, our $17.0 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 six-month periods ended June 30, 2012 and 2011, we recorded foreign currency transaction losses of $7,000 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 June 30, 2012, we had approximately $793,000 of derivative liabilities recorded on our balance sheet related to 333,333 Series GG warrants. A hypothetical 50% increase in our stock price would increase the value of our derivative liabilities by approximately $556,000. A hypothetical 50% decrease in our stock price would decrease the value of our derivative liabilities by approximately $502,000.

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 June 30, 2012. Disclosure controls and procedures

include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive and principal financial officers, as appropriate, to allow timely decisions regarding required disclosure. Based on our evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of the end of the period covered by this report, our disclosure controls and procedures are adequately designed and are effective.

Our management, including our Chief Executive Officer and Chief Financial Officer, understands that our disclosure controls and procedures do not guarantee that all errors and all improper conduct will be prevented. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute assurance that the objectives of the control systems are met. Further, a design of a control system must reflect the fact that there are resource constraints, and the benefit of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of improper conduct, if any, have been detected. These inherent limitations include the realities that judgments and decision-making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more persons, or by management override of the control. Further, the design of any system of controls is also based in part upon assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations of a cost-effective control system, misstatements due to error or fraud may occur and may not be detected.

Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles, and includes those policies and procedures that:

- pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles and that receipts and expenditures of the company are being made only in accordance with authorization of management and directors of the company; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company's assets that could have a material effect on the financial statements.

Changes in Control Over Financial Reporting

During the quarter ended June 30, 2012, there were no changes in our internal control over financial reporting that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1A. Risk Factors

There have been the following material changes to the Company's risk factors as previously disclosed in the Company's Annual Report on Form 10-K for the year ended December 31, 2011, filed with the SEC on March 7, 2012:

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

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

Our near-term financial success depends in large part on obtaining regulatory approval to market Lymphoseek in the U.S. The NDA for Lymphoseek, intended for use in intraoperative lymphatic mapping across a broad range of cancers, is currently under review by 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 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 did not receive FDA approval of Lymphoseek by the June 30, 2012 deadline established in the Loan Agreement with Hercules, and therefore expect that additional loan proceeds of up to $3 million thereunder may not be available to us under the current terms.

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

(a) During the three-month period ended June 30, 2012, an investor exercised a total of 20,000 Series V Warrants in exchange for issuance of 20,000 shares of our common stock, resulting in gross proceeds of $6,200. The issuance of the shares was exempt from registration under Sections 4(2) and 4(6) of the Securities Act and Regulation D.

(b) The following table provides information regarding repurchases of our common stock during the three-month period ended June 30, 2012.

Period	Total Number of Shares Purchased [1]	Average Price Paid Per Share [2]
Month #1 (April 1, 2012 through April 30, 2012)	37,500	$ 2.69
Month #2 (May 1, 2012 through May 31, 2012)	—	—
Month #3 (June 1, 2012 through June 30, 2012)	—	—
Total	37,500	$ 2.69

(1) In April 2012, our Board of Directors authorized the repurchase of 37,500 shares of common stock from certain executives for the purpose of meeting their personal tax obligations.

(2) The price paid per share was equal to the closing market price of the Company's common stock on the trading day prior to the date of the repurchase.

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.**

101.INS XBRL Instance Document**

101.SCH XBRL Taxonomy Extension Schema Document**

101.CAL XBRL Taxonomy Extension Calculation Linkbase Document**

101.DEF XBRL Taxonomy Extension Definition Linkbase Document**

101.LAB XBRL Taxonomy Extension Label Linkbase Document**

101.PRE XBRL Taxonomy Extension Presentation Linkbase Document**

* Filed herewith.
** Furnished herewith.

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

SIGNATURES

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

NAVIDEA BIOPHARMACEUTICALS, INC.
(the Company)
Dated: August 9, 2012

By: /s/ Mark J. Pykett

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

By: /s/ Brent L. Larson

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

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*Filed herewith.
**Furnished herewith.

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