NAVIDEA BIOPHARMACEUTICALS, INC.
Form 10-Q
May 10, 2013

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**FORM 10-Q**

(Mark One)

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

For the quarterly period ended March 31, 2013

or

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

For the transition period from _____ to _____

Commission File Number: 001-35076

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

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

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

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

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

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

Yes x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes x No ¨

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

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

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

Yes ¨ No x

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date: 119,577,859 shares of common stock, par value $.001 per share (as of the close of business on May 3, 2013).

**NAVIDEA BIOPHARMACEUTICALS, INC. and SUBSIDIARIES**

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**PART I – Financial Information**



**PART II – Other Information**

**PART I – FINANCIAL INFORMATION**

**Item 1. Financial Statements**

**Navidea Biopharmaceuticals, Inc. and Subsidiaries**

**Consolidated Balance Sheets**

| | March 31, 2013 (unaudited) | December 31, 2012 |
|---|---|---|
| ASSETS | | |
| Current assets: | | |
| Cash | $9,845,773 | $9,118,564 |
| Accounts receivable | 17,500 | 17,605 |
| Inventory | 867,267 | 297,500 |
| Prepaid expenses and other | 1,302,982 | 1,183,714 |
| Total current assets | 12,033,522 | 10,617,383 |
| Property and equipment | 2,380,230 | 2,026,895 |
| Less accumulated depreciation and amortization | 1,165,589 | 1,092,317 |
| | 1,214,641 | 934,578 |
| Patents and trademarks | 116,604 | 115,053 |
| Less accumulated amortization | 23,373 | 22,571 |
| | 93,231 | 92,482 |
| Deferred debt issuance costs and other | 263,670 | 327,954 |
| Total assets | $13,605,064 | $11,972,397 |

**Continued**

**Navidea Biopharmaceuticals, Inc. and Subsidiaries**

**Consolidated Balance Sheets, continued**

| | March 31, 2013 (unaudited) | December 31, 2012 |
|---|---|---|
| LIABILITIES AND STOCKHOLDERS' DEFICIT | | |
| Current liabilities: | | |
| Accounts payable | $1,865,335 | $1,417,463 |
| Accrued liabilities and other | 1,193,007 | 2,016,358 |
| Notes payable, current, net of discounts of $178,759 and $202,287, respectively | 2,769,080 | 2,756,718 |
| Total current liabilities | 5,827,422 | 6,190,539 |
| Notes payable, net of discounts of $58,293 and $93,038, respectively | 10,240,613 | 6,930,112 |
| Other liabilities | 256,422 | 257,122 |
| Total liabilities | 16,324,457 | 13,377,773 |
| Commitments and contingencies | | |
| Stockholders' deficit: | | |
| Preferred stock; $.001 par value; 5,000,000 shares authorized; 6,938 Series B shares issued and outstanding at March 31, 2013 and December 31, 2012 | 7 | 7 |
| Common stock; $.001 par value; 200,000,000 shares authorized; 117,490,109 and 113,018,772 shares issued and outstanding at March 31, 2013 and December 31, 2012, respectively | 117,490 | 113,019 |
| Additional paid-in capital | 279,061,973 | 273,039,442 |
| Accumulated deficit | (281,898,863) | (274,557,844) |
| Total stockholders' deficit | (2,719,393) | (1,405,376) |
| Total liabilities and stockholders' deficit | $13,605,064 | $11,972,397 |

See accompanying notes to consolidated financial statements

**Navidea Biopharmaceuticals, Inc. and Subsidiaries**

**Consolidated Statements of Operations**

**(unaudited)**

| | Three Months Ended March 31, | |
|---|---|---|
| | 2013 | 2012 |
| Revenue | $— | $11,931 |
| Operating expenses: | | |
| Research and development | 3,639,757 | 3,943,714 |
| Selling, general and administrative | 3,364,490 | 2,574,630 |
| Total operating expenses | 7,004,247 | 6,518,344 |
| Loss from operations | (7,004,247) | (6,506,413) |
| Other income (expense): | | |
| Interest income | 1,497 | 9,733 |
| Interest expense | (363,082) | (293,671) |
| Change in derivative liabilities | — | (184,084) |
| Other | 24,813 | (14,637) |
| Total other expense, net | (336,772) | (482,659) |
| Net loss | (7,341,019) | (6,989,072) |
| Preferred stock dividends | — | (25,000) |
| Net loss attributable to common stockholders | $(7,341,019) | $(7,014,072) |
| Loss per common share (basic and diluted) | $(0.06) | $(0.07) |
| Weighted average shares outstanding (basic and diluted) | 113,763,600 | 94,074,918 |

See accompanying notes to consolidated financial statements.

**Navidea Biopharmaceuticals, Inc. and Subsidiaries**

**Consolidated Statement of Stockholders' Deficit**

**(unaudited)**

| | Preferred Stock | | Common Stock | | Additional Paid-In | Accumulated | |
|---|---|---|---|---|---|---|---|
| | Shares | Amount | Shares | Amount | Capital | Deficit | Total |
| Balance, December 31, 2012 | 6,938 | $ 7 | 113,018,772 | $113,019 | $273,039,442 | $(274,557,844) | $(1,405,376) |
| Issued stock in connection with public offering, net | — | — | 1,542,389 | 1,542 | 4,455,479 | — | 4,457,021 |
| Issued stock upon exercise of stock options, net | — | — | 39,649 | 40 | (9,201) | — | (9,161) |
| Issued restricted stock | — | — | 61,250 | 61 | — | — | 61 |
| Cancelled stock to pay tax obligations | — | — | (194,077) | (194) | (610,362) | — | (610,556) |
| Issued stock upon exercise of warrants | — | — | 3,000,000 | 3,000 | 1,377,000 | — | 1,380,000 |
| Issued stock to 401(k) plan | — | — | 22,126 | 22 | 66,755 | — | 66,777 |
| Stock compensation expense | — | — | — | — | 742,860 | — | 742,860 |
| Net loss | — | — | — | — | — | (7,341,019) | (7,341,019) |
| Balance, March 31, 2013 | 6,938 | $ 7 | 117,490,109 | $117,490 | $279,061,973 | $(281,898,863) | $(2,719,393) |

See accompanying notes to consolidated financial statements.

**Navidea Biopharmaceuticals, Inc. and Subsidiaries**

**Consolidated Statements of Cash Flows**

**(unaudited)**

| | Three Months Ended March 31, | |
|---|---|---|
| | 2013 | 2012 |
| Cash flows from operating activities: | | |
| Net loss | $(7,341,019) | $(6,989,072) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation and amortization | 76,061 | 33,919 |
| Amortization of debt discount and debt offering costs | 122,557 | 116,314 |
| Stock compensation expense | 742,860 | 418,304 |
| Change in derivative liabilities | — | 184,084 |
| Issued stock to 401(k) plan | 66,777 | — |
| Changes in operating assets and liabilities: | | |
| Accounts receivable | 2,222 | (587) |
| Inventory | (569,767) | (96,951) |
| Prepaid expenses and other assets | (121,385) | (132,270) |
| Accounts payable | 447,311 | 110,236 |
| Accrued liabilities and other liabilities | (821,345) | (235,099) |
| Net cash used in operating activities | (7,395,728) | (6,591,122) |
| Cash flows from investing activities: | | |
| Purchases of equipment | (355,321) | (141,427) |
| Patent and trademark costs | (1,552) | — |
| Net cash used in investing activities | (356,873) | (141,427) |
| Cash flows from financing activities: | | |
| Proceeds from issuance of common stock | 6,200,767 | 177,669 |
| Payment of common stock issuance costs | (324,384) | — |
| Payment of tax withholdings related to stock-based compensation | (659,018) | (4,795) |
| Payment of preferred stock dividends | — | (25,000) |
| Proceeds from notes payable | 4,000,000 | — |
| Payment of debt issuance costs | — | (153,949) |
| Principal payments on notes payable | (735,410) | — |
| Payments under capital leases | (2,145) | (1,312) |
| Net cash provided by (used in) financing activities | 8,479,810 | (7,387) |
| Net increase (decrease) in cash | 727,209 | (6,739,936) |

| | | |
|---|---|---|
| Cash, beginning of period | 9,118,564 | 28,644,004 |
| Cash, end of period | $9,845,773 | $21,904,068 |

See accompanying notes to consolidated financial statements.

**Notes to Consolidated Financial Statements**

**(unaudited)**

## 1. Summary of Significant Accounting Policies

**a.** **Basis of Presentation:** The information presented as of March 31, 2013 and for the three-month periods ended March 31, 2013 and March 31, 2012 is unaudited, but includes all adjustments (which consist only of normal recurring adjustments) that the management of Navidea Biopharmaceuticals, Inc. (Navidea, the Company, or we) believes to be necessary for the fair presentation of results for the periods presented. Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America have been condensed or omitted pursuant to the rules and regulations of the U.S. Securities and Exchange Commission. The balances as of March 31, 2013 and the results for the interim periods are not necessarily indicative of results to be expected for the year. The consolidated financial statements should be read in conjunction with Navidea's audited consolidated financial statements for the year ended December 31, 2012, which were included as part of our Annual Report on Form 10-K.

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

**b.** **Fair Value of Financial Instruments:** In accordance with current accounting standards, the fair value hierarchy prioritizes the inputs to valuation techniques used to measure fair value, giving the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to unobservable inputs (Level 3 measurements). The three levels of the fair value hierarchy are described below:

*Level 1* – Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities;

*Level 2* – Quoted prices in markets that are not active or financial instruments for which all significant inputs are observable, either directly or indirectly; and

*Level 3* – Prices or valuations that require inputs that are both significant to the fair value measurement and unobservable.

A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement. In determining the appropriate levels, we perform a detailed analysis of the assets and liabilities whose fair value is measured on a recurring basis. At each reporting period, all assets and liabilities for which the fair value measurement is based on significant unobservable inputs or instruments which trade infrequently and therefore have little or no price transparency are classified as Level 3. See Note 2.

The following methods and assumptions were used to estimate the fair value of each class of financial instruments:

**(1)** Cash, accounts receivable, accounts payable, and accrued liabilities: The carrying amounts approximate fair value because of the short maturity of these instruments.

**(2)** Notes payable: The carrying value of our debt at March 31, 2013 and December 31, 2012 is presented as the face amount of the notes less unamortized discounts. The estimated fair value of our debt was calculated using a discounted cash flow analysis, which includes Level 3 inputs such as the estimated current market interest rate for similar instruments with similar creditworthiness. At March 31, 2013, the fair value of our notes payable is approximately $13.1 million, which approximates face value. See Note 6.

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

## 2. Fair Value Hierarchy

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

## 3. Stock-Based Compensation

At March 31, 2013, we have instruments outstanding under two stock-based compensation plans; the 1996 Stock Incentive Plan (the 1996 Plan) and the Fourth Amended and Restated 2002 Stock Incentive Plan (the 2002 Plan). Currently, under the 2002 Plan, we may grant incentive stock options, nonqualified stock options, and restricted stock awards to full-time employees and directors, and nonqualified stock options and restricted stock awards may be granted to our consultants and agents. Total shares authorized under each plan are 1.5 million shares and 12 million shares, respectively. Although instruments are still outstanding under the 1996 Plan, the plan has expired and no new grants may be made from it. Under both plans, the exercise price of each option is greater than or equal to the closing market price of our common stock on the date of the grant.

Stock options granted under the 1996 Plan and the 2002 Plan generally vest on an annual basis over one to four years. Outstanding stock options under the plans, if not exercised, generally expire ten years from their date of grant or up to 90 days following the date of an optionee’s separation from employment with the Company. We issue new shares of our common stock upon exercise of stock options.

Stock-based payments to employees and directors, including grants of stock options, are recognized in the consolidated statement of operations based on their estimated fair values. The fair value of each stock option award is estimated on the date of grant using the Black-Scholes option pricing model. Expected volatilities are based on the Company’s historical volatility, which management believes represents the most accurate basis for estimating expected future volatility under the current circumstances. Navidea uses historical data to estimate forfeiture rates. The

expected term of stock options granted is based on the vesting period and the contractual life of the options. The risk-free rate is based on the U.S. Treasury yield in effect at the time of the grant.

Compensation cost arising from stock-based awards is recognized as expense over either (1) the requisite service period or (2) the estimated performance period. Restricted stock awards are valued based on the closing stock price on the date of grant and amortized ratably over the estimated life of the award. Restricted stock may vest based on the passage of time, or upon occurrence of a specific event or achievement of goals as defined in the grant agreements. In such cases, we record compensation expense related to grants of restricted stock based on management’s estimates of the probable dates of the vesting events.

For the three-month periods ended March 31, 2013 and 2012, our total stock-based compensation expense was approximately $743,000 and $418,000, respectively. We have not recorded any income tax benefit related to stock-based compensation in either of the three-month periods ended March 31, 2013 and 2012.

A summary of the status of our stock options as of March 31, 2013, and changes during the three-month period then ended, is presented below:

Three Months Ended March 31, 2013

| | **Number of Options** | **Weighted Average Exercise Price** | Weighted Average Remaining Contractual Life | **Aggregate Intrinsic Value** |
|---|---|---|---|---|
| Outstanding at beginning of period | 3,412,777 | $ 2.01 | | |
| Granted | 1,585,225 | 3.07 | | |
| Exercised | (60,000) | 0.84 | | |
| Forfeited | (45,000) | 2.62 | | |
| Expired | — | — | | |
| Outstanding at end of period | 4,893,002 | $ 2.35 | 7.7 years | $3,158,458 |
| Exercisable at end of period | 2,022,640 | $ 1.36 | 5.2 years | $2,964,259 |

A summary of the status of our unvested restricted stock as of March 31, 2013, and changes during the three-month period then ended, is presented below:

Three Months Ended March 31, 2013

| | **Number of Shares** | Weighted Average Grant-Date Fair Value |
|---|---|---|
| Unvested at beginning of period | 1,335,000 | $ 2.28 |
| Granted | 61,250 | 2.91 |

| | | |
|---|---|---|
| Vested | (660,000) | 1.74 |
| Forfeited | — | — |
| Expired | — | — |
| Unvested at end of period | 736,250 | $ 2.81 |

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

As of March 31, 2013, there was approximately $3.9 million of total unrecognized compensation expense related to unvested stock-based awards, which we expect to recognize over remaining weighted average vesting terms of 2.2 years.

**4. Earnings Per Share**

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

The following table sets forth the calculation of basic and diluted earnings (loss) per share for the three-month periods ended March 31, 2013 and 2012:

| | Three Months Ended March 31, | |
|---|---|---|
| | 2013 | 2012 |
| Net loss | $ (7,341,019) | $ (6,989,072) |
| Preferred stock dividends | — | (25,000) |
| Net loss attributable to common stockholders | $ (7,341,019) | $ (7,014,072) |
| | | |
| Weighted average shares outstanding (basic and diluted) | 113,763,600 | 94,074,918 |
| Loss per common share (basic and diluted) | $ (0.06) | $ (0.07) |

Earnings (loss) per common share for the three-month periods ended March 31, 2013 and 2012 excludes the effects of 35.1 million and 55.6 million common share equivalents, respectively, since such inclusion would be anti-dilutive. The excluded shares consist of common shares issuable upon exercise of outstanding stock options and warrants, and upon the conversion of convertible debt and convertible preferred stock.

The Company’s unvested stock awards contain nonforfeitable rights to dividends or dividend equivalents, whether paid or unpaid (referred to as “participating securities”). Therefore, the unvested stock awards are required to be included in

the number of shares outstanding for both basic and diluted earnings per share calculations. However, due to our loss from continuing operations, 736,250 and 1,856,000 shares of unvested restricted stock were excluded in determining basic and diluted loss per share for the three-month periods ended March 31, 2013 and 2012, respectively, because such inclusion would be anti-dilutive.

**5. Inventory**

All components of inventory are valued at the lower of cost (first-in, first-out) or market. We adjust inventory to market value when the net realizable value is lower than the carrying cost of the inventory. Market value is determined based on estimated sales activity and margins.

During the three-month periods ended March 31, 2013 and 2012, we capitalized $525,000 and $510,000, respectively, of inventory costs associated with our Lymphoseek product. During the three-month period ended March 31, 2012, we wrote off $74,000 of previously capitalized Lymphoseek inventory due to the consumption of the Lymphoseek material in previously unanticipated product development activities.

The components of inventory as of March 31, 2013 and December 31, 2012, net of reserves of $308,000, are as follows:

| | March 31, 2013 (unaudited) | December 31, 2012 |
|---|---|---|
| Pharmaceutical materials | $ 419,953 | $ 297,500 |
| Pharmaceutical work-in-process | 447,314 | — |
| Total | $ 867,267 | $ 297,500 |

We estimate a reserve for obsolete inventory based on management's judgment of probable future commercial use, which is based on an analysis of current inventory levels, historical and estimated future sales and production rates, and estimated shelf lives. During the three-month period ended March 31, 2012, we recorded an obsolescence reserve for $339,000 of Lymphoseek inventory due to changes in our projections of the probability of future commercial use for the specific lots previously capitalized.

6. Notes Payable

During the three-month period ended March 31, 2013, we paid $656,000 of principal payments on our note payable to Hercules Technology II, L.P. (Hercules). During the three-month periods ended March 31, 2013 and 2012, we recorded interest expense of $255,000 and $293,000, including amortization of the debt discounts and deferred financing costs related to our note payable to Hercules. As of March 31, 2013, the remaining outstanding principal balance of the Hercules debt was approximately $5.1 million.

During the three-month period ended March 31, 2013, we drew an additional $4.0 million under the Platinum Montaur Life Sciences, LLC (Montaur) credit facility and recorded interest expense of $106,000. As of March 31, 2013, the total principal amount due under the Montaur credit facility was $8.0 million.

In March 2013, the Company received FDA approval to market Lymphoseek. The approval of Lymphoseek resulted in an additional $20 million being made available to the Company under the Montaur credit facility.

7. Derivative Instruments

Certain embedded features of our convertible securities and notes payable, as well as warrants to purchase our common stock, may be treated as derivative liabilities. We do not use derivative instruments for hedging of market

risks or for trading or speculative purposes.

Changes in the estimated fair values of our derivative liabilities are recorded in the consolidated statement of operations. The net effect of marking our derivative liabilities to market during the three-month period ended March 31, 2012 resulted in net increases in non-cash expense of $184,000. No derivative liabilities were outstanding as of March 31, 2013.

## 8. Equity

During the first quarter of 2013, Navidea completed a public offering of 1,542,389 shares of the Company's common stock at a price of $3.10 per share less underwriting discounts and commissions (the February 2013 Offering). The net proceeds to the Company were approximately $4.5 million after deducting expenses associated with the February 2013 Offering. The Company will use the net proceeds from the February 2013 Offering to fund the clinical development and launch of its current drug products, to fund other potential product pipeline opportunities, and for general corporate purposes. The February 2013 Offering was underwritten by Ladenburg Thalmann & Co. Inc. and was made pursuant to the Company's existing effective shelf registration statement on Form S-3.

## 9. Stock Warrants

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

At March 31, 2013, there are 8.5 million warrants outstanding to purchase our common stock. The warrants are exercisable at prices ranging from $0.46 to $2.375 per share with a weighted average exercise price of $0.76 per share.

## 10. Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases, and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. Due to the uncertainty surrounding the realization of the deferred tax assets in future tax returns, all of the deferred tax assets have been fully offset by a valuation allowance at March 31, 2013 and December 31, 2012.

Current accounting standards include guidance on the accounting for uncertainty in income taxes recognized in the financial statements. Such standards also prescribe a recognition threshold and measurement model for the financial statement recognition of a tax position taken, or expected to be taken, and provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. The Company believes that the ultimate deductibility of all tax positions is highly certain, although there is uncertainty about the timing of such deductibility. As a result, no liability for uncertain tax positions was recorded as of March 31, 2013 or December 31, 2012 and we do not expect any significant changes in the next twelve months. Should we need to accrue interest or penalties on uncertain tax positions, we would recognize the interest as interest expense and the penalties as a selling,

general and administrative expense. As of March 31, 2013, tax years 2009-2012 remained subject to examination by federal and state tax authorities.

## 11. Supplemental Disclosure for Statements of Cash Flows

During the three-month periods ended March 31, 2013 and 2012, we paid interest aggregating $242,000 and $123,000, respectively. During the three-month period ended March 31, 2013, we issued 22,126 shares of our common stock as matching contributions to our 401(k) plan.

**12. Subsequent Event**

On April 23, 2013, Navidea completed a public offering of 2,100,000 shares of the Company's common stock at a price of $2.43 per share less underwriting discounts and commissions (the April 2013 Offering). The net proceeds to the Company were approximately $4.8 million after deducting expenses associated with the April 2013 Offering. The Company will use the net proceeds from the April 2013 Offering to fund the clinical development and launch of its current drug products, to fund other potential product pipeline opportunities, and for general corporate purposes. The April 2013 Offering was underwritten by Ladenburg Thalmann & Co. Inc. and was made pursuant to the Company's existing effective shelf registration statement on Form S-3.

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

**Forward-Looking Statements**

This report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends affecting the financial condition of our business. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including, among other things:

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

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

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

**The Company**

Navidea Biopharmaceuticals, Inc. (Navidea, the Company, or we), a Delaware corporation, is a biopharmaceutical company focused on the development and commercialization of precision diagnostics and radiopharmaceutical agents. Lymphoseek® (technetium Tc 99m tilmanocept) Injection is a novel, receptor-targeted, small-molecule, investigational radiopharmaceutical used in lymphatic mapping procedures that are performed to help evaluate patients with breast cancer and melanoma. Lymphoseek is designed to identify the lymph nodes that drain from a primary tumor, which have the highest probability of harboring cancer. It was approved for commercial sale by the U.S. Food and Drug Administration (FDA) on March 13, 2013. In addition, we are currently developing three other radiopharmaceutical agent platforms. The first, NAV4694, is a Fluorine-18 (F-18) radiolabeled positron emission tomography (PET) imaging agent being developed as an aid in the diagnosis of patients with signs or symptoms of cognitive impairment such as Alzheimer's disease (AD). The second, NAV5001, is an Iodine-123 (I-123) radiolabeled single photon emission computed tomography (SPECT) imaging agent being developed as an aid in the diagnosis of Parkinson's disease (PD) and other movement disorders, with potential use as a diagnostic aid in dementia. The third, RIGScan™, is a radiolabeled monoclonal antibody being developed as a diagnostic aid for use during surgery to help surgeons locate occult or metastatic cancer, with a primary focus on colorectal cancer. These drug product candidates 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 now-approved Lymphoseek product candidate, as well as more recently on our other pipeline programs, including NAV4694, NAV5001 and RIGScan. We expect our overall research and development expenditures to continue to be significantly higher during 2013 as compared to 2012 due to the expansion of our clinical, regulatory, and business development staff and efforts that support the commercialization of Lymphoseek, further development of NAV4694, NAV5001, and RIGScan, and the potential sourcing and development of additional pipeline product candidates. The level to which the expenditures rise will depend on the extent to which we are able to execute on these strategic development initiatives.

*Lymphoseek*

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

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

Moreover, multiple level nodal dissection of patients in the trial with cancer-positive lymph nodes led to an average removal of 38 lymph nodes per patient, whereas Lymphoseek on average led to the identification of approximately 4 lymph nodes, representing a substantial reduction in potential morbidity for patients with head and neck cancer undergoing sentinel lymph node biopsy, as well as potentially enabling reductions in the time and cost of surgery. The NEO3-06 clinical study was designed to demonstrate the performance of Lymphoseek in head and neck cancer as well as to potentially expand the product label for Lymphoseek as a sentinel lymph node biopsy agent after the initial marketing clearance for the product. We anticipate filing a supplemental New Drug Application for Lymphoseek in the U.S. for use in sentinel lymph node biopsy by the end of 2013.

Navidea was advised in February 2012 by the European Medicines Agency (EMA) Committee for Medicinal Products for Human Use (CHMP) that the Committee had adopted the advice of the Scientific Advice Working Party (SAWP) regarding the Lymphoseek development program and determined that Lymphoseek is eligible for a Marketing Authorization Application (MAA) submission based on clinical data accumulated from completed pivotal studies and supporting clinical literature. We submitted our MAA for Lymphoseek to the EMA in December 2012. We cannot assure you that Lymphoseek will achieve regulatory approval in the EU or any market outside the U.S. or if approved, that it will achieve market acceptance in any market.

*NAV4694*

NAV4694 is a Fluorine-18 labeled precision radiopharmaceutical candidate for use in the imaging and evaluation of patients with signs or symptoms of cognitive impairment such as AD. NAV4694 binds to beta-amyloid deposits in the brain that can then be imaged in PET scans. Amyloid plaque pathology is a required feature of AD and the presence of amyloid pathology is a supportive feature for diagnosis of probable AD. Patients who are negative for amyloid pathology do not have AD.

Based on the data accumulated thus far, NAV4694 appears to have better sensitivity and specificity in detecting beta-amyloid than other agents developed to date. Due to its high affinity for amyloid, improved contrast, and enhanced uptake in the amyloid-target regions of interest in the brain compared with low uptake in white matter background, better signal-to-noise ratios have been observed. Greater contrast and better signal-to-noise ratios may enable the ability to detect smaller amounts of amyloid and earlier identification of disease, as well as the opportunity to detect smaller changes in amyloid levels and monitor disease progression over time.

NAV4694 has been studied in rigorous pre-clinical studies and several clinical trials in humans. Clinical studies through Phase 2 have included over 140 subjects to date. Results suggest that NAV4694 has the potential ability to image patients quickly and safely with high sensitivity and specificity. We are currently supporting a Phase 2 trial that we initiated in September 2012, primarily to expand the safety database for the compound, and a Phase 2b trial in subjects with mild cognitive impairment in March 2013. We also expect to initiate a Phase 3 autopsy-based trial by mid-2013 to support registration in the U.S. and the EU. We cannot assure you, however, that further clinical trials for this product will be successful, that it will achieve regulatory approval, or if approved, that it will achieve market acceptance.

*NAV5001*

NAV5001 is a patented Iodine-123 labeled small molecule radiopharmaceutical used with SPECT imaging to identify the status of specific regions in the brains of patients suspected of having PD. The agent binds to the dopamine

transporter (DAT) on the cell surface of dopaminergic neurons in the striatum and substantia nigra regions of the brain. Loss of these neurons is a hallmark of PD.

NAV5001 has been administered to over 600 subjects to date. Results from clinical trials have demonstrated that NAV5001 has high affinity for DAT and rapid kinetics which enable the generation of clean images quickly, beginning within about 20 minutes after injection, while other agents typically have waiting periods from 4 to 24 hours before imaging can occur. In addition to its potential use as an aid in the differential diagnosis of PD and movement disorders, NAV5001 may also be useful in the diagnosis of Dementia with Lewy Bodies (DLB), one of the most common forms of dementia after AD. We initiated our Phase 2b program in DLB in April 2013, commencing an investigator-initiated study. We expect to initiate a Company-sponsored Phase 2b study later in 2013. We also expect to initiate a Phase 3 trial in subjects with PD in the second half of 2013. We cannot assure you, however, that further clinical trials for this product will be successful, that it will achieve regulatory approval, or if approved, that it will achieve market acceptance.

*RIGScan*

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

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

To support resuming RIGScan development, we filed a new investigational new drug (IND) request with the FDA in late 2010. We held a pre-IND meeting with the FDA in February 2011 to define the basic chemistry, manufacturing and control (CMC) requirements needed to resume clinical development efforts on RIGScan. The FDA provided guidance regarding enhancing our manufacturing platform, including process improvements to increase manufacturing efficiency and the quality of the underlying biologic antibody and potentially transitioning from a murine-based antibody to a human-based antibody. In August 2011, we also held a meeting with the SAWP of the EMA and received similar guidance. With this collective guidance, we have transitioned from a murine antibody used in the previous studies noted above to a humanized antibody. In September 2012, we were awarded a grant from the National Institutes of Health (NIH) to further the development of RIGScan. The first phase of the grant, which has been awarded, is for $315,000; the second phase of the grant, which requires that we meet certain conditions, primarily investigational review board approval, will be for an additional $1.2 million. We have focused on manufacturing the humanized antibody with the aim of completing the necessary manufacturing steps to support the start of clinical development; however, as the scope and required resources for the RIGScan program, particularly in light of other development opportunities such as Lymphoseek, NAV4694, NAV5001, or other agents continues to be assessed, the timing and scope of our plans for RIGScan may be further affected.

RIGScan is a biologic drug that has not been produced for several years. We have completed the initial steps in assessing the materials required for future clinical testing. We will need to establish robust manufacturing and radiolabeling capabilities for the antibody in order to meet the regulatory needs for the RIGScan product. We cannot assure you that further clinical development will be successful, that the FDA or the EMA will clear RIGScan for marketing, or that it will be successfully introduced or achieve market acceptance.

**Outlook**

With the U.S. approval of Lymphoseek in March 2013, the Company has now undertaken the commercial launch in the U.S. with our marketing partner, Cardinal Health, which we announced on May 1, 2013. As such, we expect to report revenue from Lymphoseek beginning in the second quarter of 2013. However, as we do not yet have experience and insight into the level of potential sales success we may achieve with Lymphoseek, we do not currently expect to provide revenue guidance for 2013.

Our operating expenses over the last three years have been focused primarily on support of Lymphoseek and NAV4694 product development, and to a lesser extent, on efforts to restart active development of RIGScan. In addition, during 2012 we paid $1.8 million in option and sublicense fees ($1.1 million of which was non-cash in nature) related to a sublicense agreement with Alseres Pharmaceuticals, Inc. for the exclusive worldwide license of NAV5001.

We spent approximately $3.6 million and $3.9 million on research and development activities during the three-month periods ended March 31, 2013 and 2012, respectively. Following the sale of the GDS Business, our entire organization is now focused on the development of radiopharmaceutical agents that fulfill our vision of becoming a leader in precision diagnostics. Of the total amounts we spent on research and development during those periods, excluding costs related to our internal research and development headcount and our general and administrative staff which we do not currently allocate among the various development programs that we have underway, we incurred charges by program as follows:

| | Three Months Ended March 31, | |
|---|---|---|
| Development Program | 2013 | 2012 |
| Lymphoseek | $785,495 | $1,685,784 |
| NAV4694 | 781,453 | 155,280 |
| NAV5001 | 137,963 | 582,723 |
| RIGScan | 50,000 | 320,493 |

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

Lymphoseek was approved and indicated for use in lymphatic mapping for breast cancer and melanoma by the FDA in March 2013. During the remainder of 2013, we expect marketing and medical education expenses related to Lymphoseek to increase following the commercial launch in May 2013. Although our marketing partner will bear the direct marketing, sales and distribution costs related to the sale of Lymphoseek, we do expect that our costs to support product launch and medical education-related activities associated with Lymphoseek could approach approximately $5-6 million in out-of-pocket charges in 2013, compared to approximately $3 million in 2012. We also expect to incur additional development expenses related to supporting the MAA review of Lymphoseek in the EU, our NEO3-06 clinical trial and studies to support Lymphoseek in a potential post-commercialization setting, and support the other product activities related to the potential marketing registration of Lymphoseek in other markets. We cannot assure you that Lymphoseek will achieve regulatory approval in the EU or any other market outside the U.S., or if approved, that it will achieve market acceptance.

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

We expect to incur significant expenses for NAV5001 during the remainder of 2013 related to initiation and support of Phase 2 and Phase 3 clinical trials, as well as for manufacturing-related activities required to support clinical activities and to prepare to file for regulatory clearance to market. NAV5001 is not expected to generate revenue for the Company until 2016 at the earliest. We cannot assure you that 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. In the near-term, our development efforts related to RIGScan will likely be limited to those which we are able to fund through external sources such as the Small Business Innovation Research grant from the National Institutes of Health we were awarded in 2012. We believe that the time required for continued development, regulatory approval and commercialization of a RIGScan product would likely be a minimum of five years before we receive any significant product-related royalties or revenues. We cannot assure you that we will be able to complete satisfactory development arrangements or obtain incremental financing to fund development of the RIGS technology and cannot guarantee that such arrangements could be obtained on a timely basis on terms acceptable to us, or at all. We also cannot assure you that further clinical development will be successful, that the FDA or the EMA will clear RIGScan for marketing, or that it will be successfully introduced or achieve market acceptance.

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

**Results of Operations**

Since our radiopharmaceuticals are not yet generating commercial revenue, the discussion of our revenue focuses on the grant and other revenue we have received, and our operating variances focus on our radiopharmaceutical development programs and the supporting general and administrative expenses.

Three Months Ended March 31, 2013 and 2012

*Revenue.* We did not recognize any revenue during the first quarter of 2013. Revenue of $12,000 during the first quarter of 2012 was related to an Ohio Third Frontier grant to support student internships.

*Research and Development Expenses.* Research and development expenses decreased $304,000, or 8%, to $3.6 million during the first quarter of 2013 from $3.9 million during the same period in 2012. The decrease was primarily due to net decreases in drug project expenses related primarily to (i) a net decrease in Lymphoseek development costs resulting from the reserve for obsolescence related to previously capitalized Lymphoseek inventory of $339,000 and consulting costs related to preparation for a potential FDA Advisory Committee meeting of $328,000, both incurred in the first quarter of 2012, decreased manufacturing-related costs of $273,000, decreased regulatory consulting costs of $133,000, and decreased clinical trial costs of $80,000, offset by a UCSD milestone fee related to the FDA approval of Lymphoseek of $244,000 in the first quarter of 2013; (ii) a net decrease in NAV5001 development costs resulting from the $500,000 license option fee and due diligence activities of $70,000 recorded in the first quarter of 2012, offset by increased clinical activity costs of $100,000 and increased manufacturing-related activities of $25,000; (iii) a

net decrease in RIGScan manufacturing-related development costs of $270,000; and (iv) decreased consulting costs related to potential pipeline products of $100,000; offset by (v) increased NAV4694 development costs including manufacturing-related activities of $335,000 and clinical trial costs of $270,000. The net decrease in research and development expenses also included increased compensation of $742,000 related to increased headcount required for expanded development efforts and other related expenses such as incentive-based compensation and increased travel and other support costs.

*Selling, General and Administrative Expenses.* Selling, general and administrative expenses increased $790,000, or 31%, to $3.4 million during the first quarter of 2013 from $2.6 million during the same period in 2012. The net increase was primarily due to increased compensation costs of $434,000 related to increased headcount and incentive-based compensation, increased medical education costs to support Lymphoseek of $290,000, increased insurance, depreciation, and other expenses to support the increased headcount of $132,000, and increased investor relations costs of $131,000, offset by decreased out-of-pocket marketing costs related to the commercial launch of Lymphoseek of $268,000.

*Other Income (Expense).* Other expense, net, was $337,000 during the first quarter of 2013 as compared to $483,000 during the same period in 2012. During the first quarter of 2012, we recorded charges of $184,000 related to the increases in derivative liabilities resulting from the requirement to mark our derivative liabilities to market. Interest expense increased $69,000 to $363,000 during the first quarter of 2013 from $294,000 for the same period in 2012, due to the draws on the Montaur credit facility that we received during the 4th quarter of 2012, offset by the decreasing balance of the note payable we entered into in December 2011. Of this interest expense, $123,000 and $116,000 in the first quarter of 2013 and 2012, respectively, was non-cash in nature related to the amortization of debt issuance costs as well as discounts resulting from the warrants issued and conversion features embedded in the note payable.

**Liquidity and Capital Resources**

Cash balances increased to $9.8 million at March 31, 2013 from $9.1 million at December 31, 2012. The net increase was primarily due to net proceeds from the issuance of common stock of $5.9 million and draws on our Montaur credit facility of $4.0 million, offset by cash used to fund our operations, mainly for research and development activities, of $7.4 million, principal payments on our notes payable of $735,000, payment of minimum tax withholdings related to stock-based compensation of $659,000, and purchases of equipment of $355,000. The current ratio increased to 2.1:1 at March 31, 2013 from 1.7:1 at December 31, 2012.

*Operating Activities.* Cash used in operations increased $805,000 to $7.4 million during the first quarter of 2013 compared to $6.6 million during the same period in 2012.

Inventory levels increased to $867,000 at March 31, 2013 from $298,000 at December 31, 2012. An increase in pharmaceutical materials was related to completion of a new lot of Lymphoseek drug substance, a portion of which was transferred to pharmaceutical work-in-process to begin manufacturing a new lot of Lymphoseek finished drug. We expect inventory levels to increase over the remainder of 2013 as we produce additional Lymphoseek inventory following product launch.

Prepaid expenses and other current assets increased to $1.3 million at March 31, 2013 from $1.2 million at December 31, 2012, primarily due to prepayments to our third party manufacturers of Lymphoseek inventory and funding our prepaid corporate credit card.

Accounts payable increased to $1.9 million at March 31, 2013 from $1.4 million at December 31, 2012, primarily due to normal fluctuations in timing of receipt and payment of invoices. Accrued liabilities and other current liabilities decreased to $1.2 million at March 31, 2013 from $2.0 million at December 31, 2012, primarily due to payment of the 2012 bonuses and decreases in accrued Lymphoseek and NAV4694 development costs. Our payable and accrual balances will continue to fluctuate but will likely increase overall as we increase our level of commercial and

development activity related to Lymphoseek, and development activity related to NAV4694, NAV5001, RIGScan, and other potential product candidates.

*Investing Activities.* Investing activities used $357,000 during the first quarter of 2013 compared to using $141,000 during the same period in 2012. Capital expenditures of $355,000 during the first quarter of 2013 were primarily for equipment to be used in the production of NAV4694 and Lymphoseek and software. Capital expenditures of $141,000 during the first quarter of 2012 were primarily for software, equipment to be used in the production of Lymphoseek, computers, and furniture and fixtures for the new branch office in Andover, MA. We expect our overall capital expenditures for the remainder of 2013 will be higher than in 2012 as we expand our offices to accommodate anticipated headcount additions. Payments for patent and trademark costs were $2,000 during the first quarter of 2013.

*Financing Activities.* Financing activities provided $8.5 million during the first quarter of 2013 compared to $7,000 used during the same period in 2012. The $8.5 million provided by financing activities in the first quarter of 2013 consisted primarily of proceeds from the issuance of common stock of $6.2 million and proceeds from notes payable of $4.0 million, offset by principal payments on our notes payable of $735,000, payment of minimum tax withholdings related to stock-based compensation of $659,000, and payment of common stock issuance costs of $324,000. The $7,000 used by financing activities in the first quarter of 2012 consisted primarily of payments of debt issuance costs of $154,000 and payment of preferred stock dividends of $25,000, offset by net proceeds from the issuance of common stock of $173,000.

*Hercules Debt*

In December 2011, we executed a Loan and Security Agreement (the Loan Agreement) with Hercules Technology II, L.P. (Hercules). Pursuant to the Loan Agreement, we issued Hercules: (1) a Secured Term Promissory Note in the principal amount of $7,000,000, bearing interest at the greater of either (a) the U.S. Prime Rate as reported in The Wall Street Journal plus 6.75%, or (b) 10.0% (effective interest rate at March 31, 2013 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). During the first quarter of 2013, we paid $656,000 of principal payments on the Hercules debt. As of March 31, 2013, the remaining outstanding principal balance of the debt was approximately $5.1 million, and the Series GG warrant remains outstanding.

*Montaur Credit Facility*

In July 2012, we entered into an agreement with Montaur to provide us with a credit facility of up to $50 million. With the recent approval of Lymphoseek, Montaur is currently committed under the terms of the agreement to extend up to $35 million in debt financing to the Company at an interest rate equal to the greater of (a) the U.S. Prime Rate as reported in the Wall Street Journal plus 6.75%; (b) 10.0%; or (c) the highest rate of interest then payable pursuant to the Hercules Loan Agreement plus 0.125% (effective interest rate at March 31, 2013 was 10.125%). Through May 3, 2013, we have drawn a total of $8.0 million under the facility. The agreement also provides for Montaur to extend an additional $15 million on terms to be negotiated. Principal amounts are due the earlier of two years from the date of draw or June 30, 2016. No conversion features or warrants are associated with the facility. During the first quarter of 2013, we drew a total of $4.0 million under the credit facility and recorded interest expense of $106,000. As of March 31, 2013, the total principal amount due under the credit facility was $8.0 million.

*2013 Public Offerings*

We filed a shelf registration statement in 2011 to provide us with future funding alternatives and flexibility as we execute on our plans to achieve our product development and commercialization goals, as well as evaluating and acting on opportunities to expand our product pipeline. In February 2013, Navidea completed a public offering of 1,542,389 shares of the Company’s common stock at a price of $3.10 per share less underwriting discounts and commissions (the February 2013 Offering). The net proceeds to the Company were approximately $4.5 million after deducting expenses associated with the February 2013 Offering. In April 2013, Navidea completed another public offering of 2,100,000 shares of the Company’s common stock at a price of $2.43 per share less underwriting discounts and commissions (the April 2013 Offering, and collectively with the February 2013 Offering, the 2013 Offerings). The net proceeds to the Company were approximately $4.8 million after deducting expenses associated with the April 2013 Offering. The Company will use the net proceeds from the 2013 Offerings to fund the clinical development and launch of its current drug products, to fund other potential product pipeline opportunities, and for general corporate purposes. The 2013 Offerings were underwritten by Ladenburg Thalmann & Co. Inc. and were made pursuant to the

Company's existing effective shelf registration statement on Form S-3.

*Summary*

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

We believe that our credit facility with Montaur, anticipated revenue deriving from U.S. sales of Lymphoseek following the recent commercial launch, and our access to capital markets through our shelf registration provide us with access to adequate financial resources to continue to fund our business plan. However, we cannot assure you that Lymphoseek will generate our expected levels of sales and cash flow.

We will continue to evaluate our timelines and strategic needs, and although we have not decided whether, when or how much additional capital might be raised under the shelf registration statement or drawn under the Montaur 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.

**Recent Accounting Developments**

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

**Critical Accounting Policies**

*We base our management's discussion and analysis of financial condition and results of operations, as well as disclosures included elsewhere in this Quarterly Report on Form 10-Q, upon our consolidated financial statements, which we have prepared in accordance with U.S. generally accepted accounting principles. We describe our significant accounting policies in the notes to the audited consolidated financial statements contained in our Annual Report on Form 10-K. We include within these policies our "critical accounting policies." Critical accounting policies are those policies that are most important to the preparation of our consolidated financial statements and require management's most subjective and complex judgment due to the need to make estimates about matters that are inherently uncertain. Changes in estimates and assumptions based upon actual results may have a material impact on our results of operations and/or financial condition.*

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

*Research and Development.* Research and development (R&D) expenses include both internal R&D activities and external contracted services. Internal R&D activity expenses include salaries, benefits, and stock-based compensation, as well as travel, supplies, and other costs to support our R&D staff. External contracted services include clinical trial activities, CMC-related activities, and regulatory costs. R&D expenses are charged to operations as incurred. We review and accrue R&D expenses based on services performed and rely upon estimates of those costs applicable to the stage of completion of each project.

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

- *Stock-Based Compensation*. Stock-based payments to employees and directors, including grants of stock options and restricted stock, are recognized in the statements of operations based on their estimated fair values on the date of grant. The fair value of each option award is estimated on the date of grant using the Black-Scholes option pricing model to value share-based payments and the portion that is ultimately expected to vest is recognized as compensation expense over either (1) the requisite service period or (2) the estimated performance period. The determination of fair value using the Black-Scholes option pricing model is affected by our stock price as well as assumptions regarding a number of complex and subjective variables, including expected stock price volatility, risk-free interest rate, expected dividends and projected employee stock option behaviors. We estimate the expected term based on the contractual term of the awards and employees' exercise and expected post-vesting termination behavior. The restricted stock awards are valued based on the closing stock price on the date of grant and amortized ratably over the estimated life of the award.

Since stock-based compensation is recognized only for those awards that are ultimately expected to vest, we have applied an estimated forfeiture rate to unvested awards for the purpose of calculating compensation cost. These estimates will be revised, if necessary, in future periods if actual forfeitures differ from estimates. Changes in forfeiture estimates impact compensation cost in the period in which the change in estimate occurs.

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk

*Interest Rate Risk.* As of March 31, 2013, our $9.8 million in cash was primarily invested in interest-bearing money market accounts. Due to the low interest rates being realized on these accounts, we believe that a hypothetical 10% increase or decrease in market interest rates would not have a material impact on our consolidated financial position, results of operations or cash flows.

We also have exposure to changes in interest rates on our variable-rate debt obligations. As of March 31, 2013, the interest rate on the majority of our debt obligations was based on the U.S. prime rate. Based on the amount of our variable rate borrowings at March 31, 2013, which totaled approximately $13.1 million, an immediate one percentage point increase in the U.S. prime rate would increase our annual interest expense by approximately $130,000. This estimate assumes that the amount of variable rate borrowings remains constant for an annual period and that the interest rate change occurs at the beginning of the period. Because our debt obligations are currently subject to the minimum interest rates defined in the loan agreements, a decrease in the U.S. prime rate would not affect our annual interest expense.

*Foreign Currency Exchange Rate Risk.* We do not currently have material foreign currency exposure related to our assets as the majority are denominated in U.S. currency and our foreign-currency based transaction exchange risk is not material. For the three-month periods ended March 31, 2013 and 2012, we recorded foreign currency transaction losses of approximately $16,000 and $5,000, 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 market price of Company stock. As of March 31, 2013, we did not have any derivative liabilities recorded on our balance sheet. As such, we do not believe we are exposed to any equity price risk related to derivative instruments.

Item 4. Controls and Procedures

**Disclosure Controls and Procedures**

We maintain disclosure controls and procedures designed to ensure that information required to be disclosed in reports filed under the Exchange Act is recorded, processed, summarized, and reported within the specified time periods. As a part of these controls, our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) under the Exchange Act.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Exchange Act) as of March 31, 2013. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive and principal financial officers, as appropriate, to allow timely decisions regarding required disclosure. Based on our evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of the end of the period covered by this report, our disclosure controls and procedures are adequately designed and are effective.

Our management, including our Chief Executive Officer and Chief Financial Officer, understands that our disclosure controls and procedures do not guarantee that all errors and all improper conduct will be prevented. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute assurance that the objectives of the control systems are met. Further, a design of a control system must reflect the fact that there are resource

constraints, and the benefit of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of improper conduct, if any, have been detected. These inherent limitations include the realities that judgments and decision-making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more persons, or by management override of the control. Further, the design of any system of controls is also based in part upon assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations of a cost-effective control system, misstatements due to error or fraud may occur and may not be detected.

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

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

**Changes in Control Over Financial Reporting**

During the quarter ended March 31, 2013, there were no changes in our internal control over financial reporting that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**PART II - OTHER INFORMATION**

**Item 1A. Risk Factors**

There have been no 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, 2012, filed with the SEC on March 18, 2013.

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

During the three-month period ended March 31, 2013, Platinum Montaur Life Sciences, LLC exercised 3,000,000 Series X warrants in exchange for the issuance of 3,000,000 shares of our common stock, resulting in gross proceeds of $1,380,000. The issuance of the shares was exempt from registration under Section 4(a)(2) of the Securities Act and Regulation D promulgated thereunder.

**Issuer Purchases of Equity Securities**

The following table provides information regarding our repurchases of our common stock during the quarter ended March 31, 2013.

| Period | (a) Total Number of Shares Purchased | (b) | (c) Total Number of Shares Purchased | (d) Maximum Number (or Approximate Dollar Value) of Shares That May Yet Be Purchased Under the Plans or Programs |
|---|---|---|---|---|

| | Number of Shares Purchased (1) | Average Price Paid Per Share (2) | as Part of Publicly Announced Programs | |
|---|---|---|---|---|
| Month #1 (January 1 through January 31) | — | $ — | — | — |
| Month #2 (February 1 through February 28) | 34,074 | 3.08 | — | — |
| Month #3 (March 1 through March 31) | 160,003 | 3.16 | — | — |
| Total | 194,077 | $ 3.15 | — | — |

(1) There were 194,077 shares repurchased from employees for the payment of taxes in connection with the vesting of share-based payments.

(2) Average price paid per share excludes any broker commissions paid.

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.***

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**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: May 10, 2013

By: /s/ Mark J. Pykett

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

By: /s/ Brent L. Larson

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