

NAVIDEA BIOPHARMACEUTICALS, INC.  
Form 10-Q  
May 09, 2014

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

FORM 10-Q  
(Mark One)

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

For the quarterly period ended March 31, 2014

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.)

5600 Blazer Parkway, Suite 200, Dublin, Ohio

43017-7550

(Address of principal executive offices)

(Zip Code)

(614) 793-7500

(Registrant's telephone number, including area code)

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

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

Yes  No

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

Yes  No

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

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

Yes  No

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date: 150,724,574 shares of common stock, par value \$.001 per share (as of the close of business on May 2, 2014).

NAVIDEA BIOPHARMACEUTICALS, INC. and SUBSIDIARIES

INDEX

PART I – Financial Information

Item 1.	Financial Statements	<u>3</u>
	Consolidated Balance Sheets as of March 31, 2014 (unaudited) and December 31, 2013	<u>3</u>
	Consolidated Statements of Operations for the Three-Month Periods Ended March 31, 2014 and March 31, 2013 (unaudited)	<u>5</u>
	Consolidated Statement of Stockholders’ Equity for the Three-Month Period Ended March 31, 2014 (unaudited)	<u>6</u>
	Consolidated Statements of Cash Flows for the Three-Month Periods Ended March 31, 2014 and March 31, 2013 (unaudited)	<u>7</u>
	Notes to the Consolidated Financial Statements (unaudited)	<u>8</u>
Item 2.	Management’s Discussion and Analysis of Financial Condition and Results of Operations	<u>17</u>
	Forward-Looking Statements	<u>17</u>
	The Company	<u>17</u>
	Product Line Overview	<u>18</u>
	Outlook	<u>21</u>
	Results of Operations	<u>23</u>
	Liquidity and Capital Resources	<u>25</u>
	Recent Accounting Pronouncements	<u>25</u>
	Critical Accounting Policies	<u>28</u>
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	<u>30</u>
Item 4.	Controls and Procedures	<u>30</u>
PART II – Other Information		
Item 1A.	Risk Factors	<u>32</u>
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	<u>33</u>
Item 6.	Exhibits	<u>33</u>



## PART I – FINANCIAL INFORMATION

## Item 1. Financial Statements

Navidea Biopharmaceuticals, Inc. and Subsidiaries  
Consolidated Balance Sheets

ASSETS	March 31, 2014 (unaudited)	December 31, 2013
Current assets:		
Cash	\$26,006,463	\$32,939,026
Accounts receivable	586,738	1,150,626
Inventory	2,113,915	2,232,436
Prepaid expenses and other	815,816	1,009,094
Total current assets	29,522,932	37,331,182
Property and equipment	4,068,692	3,609,059
Less accumulated depreciation and amortization	1,236,779	1,483,676
	2,831,913	2,125,383
Patents and trademarks	170,357	163,302
Less accumulated amortization	27,353	26,448
	143,004	136,854
Deferred debt issuance costs and other	141,627	723,098
Total assets	\$32,639,476	\$40,316,517

Continued

Navidea Biopharmaceuticals, Inc. and Subsidiaries  
Consolidated Balance Sheets, continued

LIABILITIES AND STOCKHOLDERS' DEFICIT	March 31, 2014 (unaudited)	December 31, 2013
Current liabilities:		
Accounts payable	\$2,426,250	\$2,422,349
Accrued liabilities and other	3,019,329	4,772,963
Notes payable, current, net of discounts of \$0 and \$743,062, respectively	—	4,095,650
Total current liabilities	5,445,579	11,290,962
Notes payable, net of discounts of \$2,935,238 and \$856,746, respectively	30,939,076	23,572,603
Derivative liabilities	7,693,351	7,692,087
Other liabilities	3,169,656	1,770,452
Total liabilities	47,247,662	44,326,104
Commitments and contingencies		
Stockholders' deficit:		
Preferred stock; \$.001 par value; 5,000,000 shares authorized; 3,403 and 7,565 Series B shares issued and outstanding at March 31, 2014 and December 31, 2013, respectively	3	8
Common stock; \$.001 par value; 200,000,000 shares authorized; 149,837,919 and 135,919,423 shares issued and outstanding at March 31, 2014 and December 31, 2013, respectively	149,838	135,919
Additional paid-in capital	314,239,828	313,111,788
Accumulated deficit	(328,997,855 )	(317,257,302 )
Total stockholders' deficit	(14,608,186 )	(4,009,587 )
Total liabilities and stockholders' deficit	\$32,639,476	\$40,316,517

See accompanying notes to consolidated financial statements (unaudited).

Navidea Biopharmaceuticals, Inc. and Subsidiaries  
Consolidated Statements of Operations  
(unaudited)

	Three Months Ended March 31,	
	2014	2013
Revenue:		
Net sales	\$626,631	\$—
Grant revenue	125,173	—
Total revenue	751,804	—
Cost of goods sold	193,220	—
Gross profit	558,584	—
Operating expenses:		
Research and development	5,226,794	3,639,757
Selling, general and administrative	3,910,833	3,364,490
Total operating expenses	9,137,627	7,004,247
Loss from operations	(8,579,043 )	(7,004,247 )
Other income (expense):		
Interest income	6,793	1,497
Interest expense	(943,838 )	(363,082 )
Change in fair value of financial instruments	392,483	—
Loss on extinguishment of debt	(2,610,196 )	—
Other, net	(6,752 )	24,813
Total other expense, net	(3,161,510 )	(336,772 )
Net loss attributable to common stockholders	\$(11,740,553 )	\$(7,341,019 )
Loss per common share (basic and diluted)	\$(0.08 )	\$(0.06 )
Weighted average shares outstanding (basic and diluted)	144,783,351	113,763,600

See accompanying notes to consolidated financial statements (unaudited).

Navidea Biopharmaceuticals, Inc. and Subsidiaries  
Consolidated Statement of Stockholders' Equity  
(unaudited)

	Preferred Stock		Common Stock		Additional	Accumulated	
	Shares	Amount	Shares	Amount	Paid-In Capital	Deficit	Total
Balance, December 31, 2013	7,565	\$8	135,919,423	\$135,919	\$313,111,788	\$(317,257,302)	\$(4,009,587 )
Issued stock upon exercise of stock options, net			188,756	189	(27,903 )		(27,714 )
Issued restricted stock			120,000	120			120
Conversion of Series B preferred stock to common stock	(4,162 )	(5 )	13,609,740	13,610	(13,605 )		—
Issued warrants in connection with debt issuance					464,991		464,991
Recovery of shareholder short swing profits					11,354		11,354
Stock compensation expense					693,203		693,203
Net loss						(11,740,553 )	(11,740,553 )
Balance, March 31, 2014	3,403	\$3	149,837,919	\$149,838	\$314,239,828	\$(328,997,855)	\$(14,608,186)

See accompanying notes to consolidated financial statements (unaudited).

Navidea Biopharmaceuticals, Inc. and Subsidiaries  
Consolidated Statements of Cash Flows  
(unaudited)

	Three Months Ended March 31,	
	2014	2013
Cash flows from operating activities:		
Net loss	\$(11,740,553 )	\$(7,341,019 )
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	111,270	76,061
Loss on disposal and abandonment of assets	10,866	—
Amortization of debt discount and issuance costs	241,827	122,557
Stock compensation expense	693,203	742,860
Change in fair value of financial instruments	(392,483 )	—
Loss on extinguishment of debt	2,610,196	—
Issued stock to 401(k) plan	—	66,777
Changes in operating assets and liabilities:		
Accounts receivable	563,888	2,222
Inventory	118,521	(569,767 )
Prepaid expenses and other assets	78,533	(121,385 )
Accounts payable	3,901	447,311
Accrued liabilities and other liabilities	(1,471,562 )	(821,345 )
Net cash used in operating activities	(9,172,393 )	(7,395,728 )
Cash flows from investing activities:		
Purchases of equipment	(985,578 )	(355,321 )
Patent and trademark costs	(7,055 )	(1,552 )
Net cash used in investing activities	(992,633 )	(356,873 )
Cash flows from financing activities:		
Proceeds from issuance of common stock and short swing profits	54,674	6,200,767
Payment of common stock issuance costs	—	(324,384 )
Payment of tax withholdings related to stock-based compensation	(70,914 )	(659,018 )
Proceeds from notes payable	30,000,000	4,000,000
Payment of debt-related costs	(1,750,770 )	—
Principal payments on notes payable	(25,000,000 )	(735,410 )
Payments under capital leases	(527 )	(2,145 )
Net cash provided by financing activities	3,232,463	8,479,810
Net (decrease) increase in cash	(6,932,563 )	727,209
Cash, beginning of period	32,939,026	9,118,564
Cash, end of period	\$26,006,463	\$9,845,773

See accompanying notes to consolidated financial statements (unaudited).



Notes to the Consolidated Financial Statements (unaudited)

1. Summary of Significant Accounting Policies

**Basis of Presentation:** The information presented as of March 31, 2014 and for the three-month periods ended March 31, 2014 and 2013 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, 2014 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, 2013, which were included as part of our Annual Report on Form 10-K.

Our consolidated financial statements include the accounts of Navidea and our wholly owned subsidiaries, Navidea Biopharmaceuticals Limited and Cardiosonix Ltd. All significant inter-company accounts were eliminated in consolidation.

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

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

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

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

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

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

- (1) Cash, accounts receivable, accounts payable, and accrued liabilities: The carrying amounts approximate fair value because of the short maturity of these instruments.
- (2) Notes payable: The carrying value of our debt at March 31, 2014 and December 31, 2013 primarily consists of the face amount of the notes less unamortized discounts. See Note 6. At March 31, 2014 and December 31, 2013, certain notes payable were also required to be recorded at fair value. The estimated fair value of our debt was calculated using a discounted cash flow analysis as well as a Monte Carlo simulation. These valuation methods include Level 3 inputs such as the estimated current market interest rate for similar instruments with similar creditworthiness. Unrealized gains and losses on the fair value of the debt are classified in other expenses as a change in the fair value of financial instruments in the statements of operations. At March 31, 2014, the fair value

of our notes payable is approximately \$35.2 million, which approximates face value.

Derivative liabilities: Derivative liabilities are related to certain outstanding warrants which are recorded at fair value. The assumptions used to calculate fair value as of March 31, 2014 include volatility, a risk-free rate and (3) expected dividends. In addition, we considered non-performance risk and determined that such risk is minimal. Unrealized gains and losses on the derivatives are classified in other expenses as a change in the fair value of financial instruments in the statements of operations. See Notes 2 and 7.

Revenue Recognition: We currently generate revenue primarily from sales of Lymphoseek. Our standard shipping terms are FOB shipping point, and title and risk of loss passes to the customer upon delivery to a carrier for shipment from Cardinal Health's national distribution center to another point of destination. We generally recognize sales revenue related to sales of our products when the products are shipped. Our customers have no right to return products purchased in the ordinary course of business.

We earn additional revenues based on a percentage of the actual net revenues achieved by Cardinal Health on sales to end customers made during each fiscal year. The amount we charge Cardinal Health related to end customer sales of Lymphoseek are subject to a retroactive annual adjustment. To the extent that we can reasonably estimate the end-customer prices received by Cardinal Health, we record sales based upon these estimates at the time of sale. If we are unable to reasonably estimate end customer sales prices related to products sold, we record revenue related to these product sales at the minimum (i.e., floor) price provided for under our distribution agreement with Cardinal Health.

We generate additional revenue from grants to support various product development initiatives. We generally recognize grant revenue when expenses reimbursable under the grants have been incurred and payments under the grants become contractually due.

## 2. Fair Value Hierarchy

Beginning in the second quarter of 2013, Platinum-Montaur Life Sciences, LLC (Platinum) has the right to convert all or any portion of the unpaid principal or unpaid interest accrued on any future draws under the Platinum credit facility, under certain circumstances. Platinum's option to convert future draws into common stock was determined to meet the definition of a liability and is included as part of the value of the related notes payable on the consolidated balance sheet. The estimated fair value of the Platinum notes payable is \$3.9 million at March 31, 2014, and will continue to be measured on a recurring basis. See Note 6.

In September 2013, in connection with a Securities Purchase Agreement with Crede CG III, Ltd. (Crede), we issued warrants containing certain features that, although they do not require the warrants to be settled in cash, do require the warrants to be classified as liabilities under applicable accounting rules. See Notes 1b(3) and 7. As a result, the Company recorded a derivative liability with an estimated fair value of \$7.7 million on the date the warrants were issued. The estimated fair value of the liability remained at \$7.7 million as of March 31, 2014, and will continue to be measured on a recurring basis. See Note 7.

The following tables set forth, by level, financial liabilities measured at fair value on a recurring basis:  
Liabilities Measured at Fair Value on a Recurring Basis as of March 31, 2014

Description	Quoted Prices in Active Markets for Identical Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Balance as of March 31, 2014
Platinum notes payable	\$—	\$—	\$3,874,315	\$3,874,315
Derivative liabilities related to warrants	—	7,693,351	—	7,693,351

Liabilities Measured at Fair Value on a Recurring Basis as of December 31, 2013

Description	Quoted Prices in Active Markets for Identical Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Balance as of December 31, 2013
-------------	---	---	---	---------------------------------

Edgar Filing: NAVIDEA BIOPHARMACEUTICALS, INC. - Form 10-Q

Platinum notes payable	\$—	\$—	\$4,268,062	\$4,268,062
Derivative liabilities related to warrants	—	7,692,087	—	7,692,087

Valuation Processes-Level 3 Measurements: Depending on the instrument, the Company utilizes discounted cash flows, option pricing models, or third-party valuation services to estimate the value of their financial assets and liabilities. Valuations using discounted cash flow methods and certain option pricing models such as Black-Scholes are

9

---

generally conducted by the Company. Valuations using complex models such as Monte Carlo simulation are generally provided to the Company by third-party valuation experts. Each reporting period, the Company provides significant unobservable inputs to the third-party valuation experts based on current internal estimates and forecasts.

Sensitivity Analysis-Level 3 Measurements: Changes in the Company's current internal estimates and forecasts are likely to cause material changes in the fair value of the liabilities. The significant unobservable inputs used in the fair value measurement of the liabilities are the amount and timing of future draws expected to be taken under the Platinum Loan Agreement based on current internal forecasts, management's estimate of the likelihood of actually b. making those draws as opposed to obtaining other sources of financing, and management's estimate of the likelihood of those draws ultimately resulting in Platinum exercising their conversion option under the Platinum Loan Agreement. Significant increases (decreases) in any of the significant unobservable inputs would result in a higher (lower) fair value measurement. A change in one of the inputs would not necessarily result in a directionally similar change in the others.

There were no Level 1 liabilities outstanding at any time during the three-month periods ended March 31, 2014 and 2013. There were no transfers in or out of our Level 2 liabilities during the three-month periods ended March 31, 2014 or 2013.

### 3. Stock-Based Compensation

At March 31, 2014, 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, 2014 and 2013, our total stock-based compensation expense was approximately \$693,000 and \$743,000, respectively. We have not recorded any income tax benefit related to stock-based compensation in either of the three-month periods ended March 31, 2014 and 2013.

A summary of the status of our stock options as of March 31, 2014, and changes during the period then ended, is presented below:

	Three Months Ended March 31,			Aggregate Intrinsic Value
	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	
Outstanding at beginning of period	4,866,602	\$2.38		
Granted	1,468,230	1.77		
Exercised	(265,000 )	0.47		
Canceled and Forfeited	(4,250 )	3.02		
Expired	(120,000 )	0.53		
Outstanding at end of period	5,945,582	\$2.35	8.0 years	\$1,109,448
Exercisable at end of period	2,494,019	\$2.12	6.6 years	\$991,990

A summary of the status of our unvested restricted stock as of March 31, 2014, and changes during the period then ended, is presented below:

	Three Months Ended March 31,	
	Number of Shares	Weighted Average Grant-Date Fair Value
Unvested at beginning of period	634,250	\$2.73
Granted	120,000	1.84
Vested	(149,000 )	3.16
Forfeited	—	—
Expired	—	—
Unvested at end of period	605,250	\$2.45

In February 2014, 49,000 shares of restricted stock held by non-employee directors with an aggregate fair value of \$96,000 vested as scheduled according to the terms of the restricted stock agreements. In March 2014, 100,000 shares of restricted stock with an aggregate fair value of \$205,000 vested as scheduled according to the terms of a restricted stock agreement.

As of March 31, 2014, there was approximately \$3.1 million of total unrecognized compensation expense related to unvested stock-based awards, which we expect to recognize over remaining weighted average vesting terms of 2.0 years.

#### 4. Earnings (Loss) Per Share

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

Earnings (loss) per common share for the three-month periods ended March 31, 2014 and 2013 excludes the effects of 19.2 million and 35.1 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, 605,250 and 736,250 shares of unvested restricted stock were excluded in determining basic and diluted loss per share for the three-month periods ended March 31, 2014 and 2013, respectively, because such inclusion would be anti-dilutive.

## 5. Inventory

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

The components of inventory as of March 31, 2014 and December 31, 2013, with no reserves recorded for either period, are as follows:

	March 31, 2014	December 31, 2013
	(unaudited)	
Materials	\$642,503	\$652,818
Work-in-process	1,073,568	1,073,568
Finished goods	397,844	506,050
Total	\$2,113,915	\$2,232,436

During the three-month period ended March 31, 2013, we capitalized \$525,000 of inventory costs associated with our Lymphoseek® (technetium Tc 99m tilmanocept) Injection product. The Company capitalized no such costs during the same period in 2014. During the three-month period ended March 31, 2014, we wrote off \$10,000 of previously capitalized Lymphoseek inventory due to the consumption of the Lymphoseek material for product testing and development purposes.

We estimate a reserve for obsolete inventory based on management's judgment of probable future commercial use, which is based on an analysis of current inventory levels, estimated future sales and production rates, and estimated shelf lives. During the three-month periods ended March 31, 2014 and 2013, we recorded no obsolescence reserve for Lymphoseek inventory.

## 6. Notes Payable

In March 2014, we executed a Loan and Security Agreement (the Oxford Loan Agreement) with Oxford Finance, LLC (Oxford), providing for a loan to the Company of \$30 million. Pursuant to the Oxford Loan Agreement, we issued Oxford: (1) Term Notes in the aggregate principal amount of \$30,000,000, bearing interest at 8.5% (the Oxford Notes), and (2) Series KK warrants to purchase an aggregate of 391,032 shares of our common stock at an exercise price of \$1.918 per share, expiring in March 2021 (the Series KK warrants). We will make monthly payments of interest only commencing on April 1, 2014, and continuing on the first calendar day of each successive month thereafter through and including the first calendar day of the month immediately preceding April 1, 2015 (the Amortization Date, which may be extended to April 1, 2016, and again to April 1, 2017, if the Company achieves certain milestones associated with the Company's Lymphoseek product). Commencing on the Amortization Date, and continuing on the first calendar day of each month thereafter, the Company will make consecutive equal monthly payments of principal and interest, in arrears, to the lenders then party to the Oxford Loan Agreement based on a repayment schedule of 48 months if the Amortization Date is April 1, 2015, 36 months if the Amortization Date is April 1, 2016, and 24 months if the Amortization Date is April 1, 2017. All unpaid principal, and accrued and unpaid interest, with respect to the Oxford Notes is due and payable in full on March 1, 2019. We will also make a final payment to the lenders in an aggregate amount equal to the original principal amount of the loan multiplied by 7.95%

if the Amortization Date is April 1, 2015; 8.95% if the Amortization Date is extended to April 1, 2016; or 9.95% if the Amortization Date is extended to April 1, 2017. The Oxford Notes are 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 Oxford Loan Agreement requires that the Company adhere to certain affirmative and negative covenants, including, without limitation, financial reporting requirements and a prohibition against the incurrence of indebtedness, or creation of additional liens, other than as specifically permitted by the terms of the Oxford Loan Agreement. As of March 31, 2014, the outstanding principal balance of the Oxford Loan Agreement was \$30 million, and we were in compliance with all covenants of the Oxford Loan Agreement.

The Company recorded a debt discount related to the issuance of the Series KK Warrants and other fees to the lenders totaling \$3.0 million. Debt issuance costs directly attributable to the Oxford Loan Agreement, totaling \$118,000, were

recorded as a non-current asset on the balance sheet on the closing date. The debt discount and debt offering costs are being amortized as non-cash interest expense using the effective interest method over the term of the Oxford Loan Agreement. As of March 31, 2014, the balance of the debt discount was \$2.9 million, and the balance of the debt issuance costs was \$116,000.

Also in March 2014, in connection with the consummation of the Oxford Loan Agreement, we repaid all amounts outstanding under the General Electric Capital Corporation (GECC) and MidCap Financial SBIC, LP (MidCap) Loan and Security Agreement for a payoff amount of \$26.7 million, which included payments of \$500,000 as a pre-payment fee and \$1,000,000 as an end-of-term final payment fee.

In March 2014, in connection with entering into the Oxford Loan Agreement, we entered into a second amendment to the Platinum Loan Agreement (the Second Platinum Amendment). Concurrent with the execution of the Second Platinum Amendment, the Company delivered an Amended and Restated Promissory Note (the Second Amended Platinum Note) to Platinum, which amended and restated the First Amended Platinum Note. The Second Amended Platinum Note adjusted the interest rate to the greater of (i) the United States prime rate as reported in The Wall Street Journal plus 6.75%, (ii) 10.0%, and (iii) the highest rate of interest then payable by the Company pursuant to the Oxford Loan Agreement plus 0.125%. Navidea, Platinum, and Oxford also entered into a Subordination Agreement, providing for subordination of the Company's indebtedness under the Platinum Loan Agreement to the Company's indebtedness under the Oxford Loan Agreement, among other customary terms and conditions. As such, no payments may be made under the Platinum loan until the Oxford Notes have been paid in full and therefore, the current balance outstanding under the Platinum loan has been classified as long-term notes payable to coincide with the maturity of the Oxford Notes. The fair value of the Second Amended Platinum Note includes the estimated fair value of an embedded conversion option. The net decrease in the estimated fair value of the Second Amended Platinum Note of \$394,000 was recorded as a non-cash change in fair value of financial instruments during the three-month period ended March 31, 2014. The estimated fair value of the Second Amended Platinum Note was \$3.9 million as of March 31, 2014. As of March 31, 2014, the remaining outstanding principal balance of the Second Amended Platinum Note was approximately \$3.2 million, with \$31.8 million still available under the credit facility.

During the three-month periods ended March 31, 2014 and 2013, we recorded interest expense of \$944,000 and \$363,000, respectively, related to our notes payable. Of these amounts, \$242,000 and \$123,000, respectively, related to amortization of the debt discounts and deferred financing costs related to our notes payable.

## 7. Derivative Instruments

Certain embedded features of our convertible securities and notes payable, as well as warrants to purchase our common stock, may be treated as derivative liabilities. See Notes 1b(3) and 2. At March 31, 2014, derivative liabilities consist of the Series JJ warrants issued to Crede in September 2013. The estimated fair values of the derivative liabilities are recorded as non-current liabilities on the consolidated balance sheet. Changes in the estimated fair values of the derivative liabilities are recorded in the consolidated statement of operations as non-cash income (expense). We do not use derivative instruments for hedging of market risks or for trading or speculative purposes.

The net effect of marking the Company's derivative liabilities to market during the three-month period ended March 31, 2014 resulted in net increases in the estimated fair values of the derivative liabilities of approximately \$1,000, which were recorded as a non-cash change in the fair value of financial instruments. The total estimated fair value of our derivative liabilities was \$7.7 million as of March 31, 2014. No derivative liabilities were outstanding as of March 31, 2013.

## 8. Equity

During the three-month period ended March 31, 2014, Platinum converted 4,162 shares of their Series B Preferred Stock into 13,609,740 shares of our common stock under the terms of the Series B Preferred Stock. As of March 31, 2014, there are 3,403 shares of Series B Preferred Stock outstanding which are convertible into 11,127,810 shares of our common stock.

#### 9. Stock Warrants

In March 2014, in connection with the Oxford Loan Agreement, the Company issued Series KK warrants to purchase an aggregate of 391,032 shares of our common stock at an exercise price of \$1.918 per share, expiring in March 2021.

At March 31, 2014, there are 4.9 million warrants outstanding to purchase our common stock. The warrants are exercisable at prices ranging from \$1.92 to \$3.83 per share with a weighted average exercise price of \$3.27 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, 2014 and December 31, 2013.

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, 2014 or December 31, 2013 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, 2014, tax years 2010-2013 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, 2014 and 2013, we paid interest aggregating \$907,000 and \$242,000, 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.

In connection with entering into the Oxford Loan Agreement, we issued warrants with an estimated relative fair value of \$465,000.

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

Forward-Looking Statements

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

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

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

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

The Company

Navidea Biopharmaceuticals, Inc. (Navidea, the Company, or we), a Delaware corporation, is a biopharmaceutical company focused on the development and commercialization of precision diagnostics. Toward that end, we are currently developing five pharmaceutical platforms:

Lymphoseek® (technetium Tc 99m tilmanocept) Injection is a novel, receptor-targeted, small-molecule radiopharmaceutical used in lymphatic mapping procedures that are performed to help evaluate patients with breast cancer or melanoma. Lymphoseek is designed to identify the lymph nodes that drain from a primary tumor, which have the highest probability of harboring cancer. It was approved by the U.S. Food and Drug Administration (FDA) in March 2013, and launched commercially in the United States in May 2013.

Navidea's Manocept™ platform is predicated on the ability to specifically target the CD206 mannose receptor expressed on macrophages. This flexible and versatile platform acts as an engine for the design of purpose-built molecules offering the potential to be utilized across a range of diagnostic modalities, including single photon emission computed tomography (SPECT), positron emission tomography (PET), intra-operative and/or optical-fluorescence detection in a variety of disease states.

-

Edgar Filing: NAVIDEA BIOPHARMACEUTICALS, INC. - Form 10-Q

NAV4694 is a Fluorine-18 (F-18) radiolabeled PET imaging agent being developed as an aid in the diagnosis of patients with signs or symptoms of Alzheimer's disease (AD) and mild cognitive impairment (MCI).

NAV5001 is an Iodine-123 (I-123) radiolabeled 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.

NAV1800 (formerly 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 to date on colorectal cancer.

The last four of these drug product platforms are in development and must be cleared for marketing by the appropriate regulatory authorities before they can be sold in any markets.

## Product Line Overview

We believe that the future prospects for Navidea continue to improve as we execute our strategic vision to become a leader in precision diagnostics. Our primary development efforts over the last few years have been focused on the development of our now-approved Lymphoseek product, as well as more recently on our other pipeline programs, including NAV4694, NAV5001, NAV1800, and our Manocept platform. We expect our overall research and development expenditures to be higher during 2014 as compared to 2013 due to the advances in our clinical, regulatory, and business development programs and activities, as well as personnel, contractors and consultants that support the global registration and commercialization of Lymphoseek, further development of NAV4694, NAV5001, NAV1800, and our Manocept platform. The level to which the expenditures rise will depend on the scope, requirements and timing of these strategic development initiatives in different territories around the world.

## Lymphoseek

Lymphoseek is a lymph node targeting radiopharmaceutical agent intended for use in intraoperative lymphatic mapping procedures and lymphoscintigraphy employed in the overall diagnostic assessment of certain solid tumor cancers. Lymphoseek has the potential to provide oncology surgeons with information to identify key predictive lymph nodes that may harbor cancer and to help avoid the unnecessary removal of non-cancerous lymph nodes and the surrounding tissue in patients with a variety of solid tumor cancers. Lymphoseek was approved and indicated for use in lymphatic mapping for breast cancer and melanoma by the FDA in March 2013. Additional trials, one in head and neck cancer which was completed in 2013, an ongoing trial in colorectal cancer, and others in various stages of execution, planning or consideration, are anticipated to provide additional data to potentially support expansion of the Lymphoseek opportunity.

In December 2013, the FDA granted Fast Track designation to Lymphoseek for sentinel lymph node detection in patients with head and neck cancer and we submitted a supplemental New Drug Application (sNDA) with the FDA seeking approval for the marketing and sale of Lymphoseek for the same indication. In assessing the data-rich submission, the FDA chose to separate the filing into two applications based on the proposed labeling extensions requested and the scope of information provided. The first sNDA, aimed at Lymphoseek's use as a sentinel lymph node detection agent in patients with head and neck cancer, was accepted for review by the FDA in February 2014, and was granted Priority Review. Under the Prescription Drug User Fee Act (PDUFA), the FDA has set a target review date for the first Lymphoseek sNDA of June 16, 2014. In March 2014, the FDA accepted for review the second sNDA to support broader and more flexible use of Lymphoseek in imaging and lymphatic mapping procedures, including lymphoscintigraphy and other product capabilities. Under PDUFA, the FDA has set a target review date for the second sNDA of October 16, 2014.

In March 2014, we announced results of a three-year, voluntary follow-up study of Lymphoseek conducted in patients who participated in a Phase 3 clinical trial (NEO3-05) of the product. The primary objective of the follow-up study was to determine the regional recurrence-free rate (RRFR) after sentinel lymph node biopsy with Lymphoseek. Results of the follow-up study indicated that in patients who were confirmed to be node-negative after sentinel lymph node biopsy (n=88; 49 breast cancer, 39 melanoma) the RRFR was 98.8% (100% in breast cancer; 97.4% in melanoma) and the disease-specific survival rate was 98.6% (97.8% in breast cancer; 100% in melanoma) at three years.

An investigator-initiated study is currently underway at the University of California, San Diego (UCSD) to address the issue of injection site pain between two radiopharmaceuticals that are commonly used in lymphatic mapping procedures. The study is designed to determine if patients receiving Lymphoseek experience the same or less pain following injection compared to radiolabeled sulfur colloid, and to measure the amount of discomfort that patients report during and after injection, as well as other characteristics of performance.



We are currently pursuing registration of Lymphoseek in the European Union (EU). We submitted our Marketing Authorization Application (MAA) for Lymphoseek to the European Medicines Agency (EMA) in December 2012. In December 2013, the EMA provided updated feedback on the MAA as it continued its review. The updated feedback was limited to supplemental product specification data and the NEO3-06 Phase 3 study in head and neck cancer. In March 2014, we held an update meeting with the EMA where we presented oral explanations to the Committee for Medicinal Products for Human Use (CHMP) relating to open questions on the Lymphoseek MAA. At the conclusion of the meeting, the CHMP informed Navidea that the Committee will continue with its review of the MAA and provided the Company with additional questions, which we are currently addressing. The Company anticipates that the CHMP will convene the Scientific Advisory Group on Oncology (SAG-O) during the third quarter of 2014 to discuss additional elements of the Lymphoseek clinical study in patients with head and neck cancer. The SAG-O meeting will provide an opportunity for Navidea and independent experts in head and neck cancer surgery to review clinical data in the MAA filing and discuss broad aspects of care for patients with head and neck cancer in Europe. During this process, the MAA remains active and the review clock will continue to be stopped while Navidea works

with the CHMP to continue expanded discussions. A positive opinion for approval would enable commercialization in the EU subsequent to European Commission (EC) adoption of the CHMP opinion and pricing determinations on a country-by-country basis in each member state, a process which could take several months. However, we cannot assure you that Lymphoseek will achieve regulatory approval in the EU or any market outside the U.S., or if approved, that it will achieve market acceptance in any market.

#### Manocept Platform

Navidea's Manocept platform is predicated on the ability to specifically target the CD206 mannose receptor expressed on macrophages. Macrophages play important roles in many disease states and are an emerging target in many diseases where diagnostic uncertainty exists. This flexible and versatile platform acts as an engine for purpose-built molecules that may enhance diagnostic accuracy, clinical decision-making and ultimately patient care, while offering the potential to utilize a breadth of diagnostic modalities, including SPECT, PET, intra-operative and/or optical-fluorescence detection. The Company's FDA-approved precision diagnostic lymphatic mapping agent, Lymphoseek, is representative of the ability to successfully exploit this mechanism to develop powerful new diagnostic agents.

In February 2014, data utilizing compounds from our Manocept platform in models of rheumatoid arthritis (RA) were presented by representatives from The Ohio State University at a Keystone Symposia on Molecular Cell Biology of Macrophages in Human Disease. The studies demonstrate the ability of Cy3-tilmanocept to identify and localize to disease-state macrophages when administered intravenously, enabling detection of immune-mediated arthritis in affected joints in vivo in mice. Results were confirmed using histopathology. The data highlighted the identification of immune-mediated inflammation seen in arthritic elbows and knees of arthritis-affected mice but not in control mice or un-affected joints within arthritic mice. The imaging results in this study showed preferential localization of macrophages by Cy3-tilmanocept in affected joints with little to no localization in unaffected joints.

In April 2014, collaborators from the University of California, San Francisco presented results at the 2014 American Association for Cancer Research conference, highlighting the potential utility of imaging agents derived from the Manocept platform in identifying affected tissues and lymph nodes in patients with Kaposi Sarcoma (KS). The investigators concluded that, based on the results obtained, labeled imaging agents from the CD206-targeting Manocept platform provide potential avenues to enhance diagnosis and staging in this disorder.

The Company continues to evaluate emerging data in other disease states to define areas of focus, development pathways and partnering options to capitalize on the Manocept platform. We cannot assure you that further evaluation or development will be successful, that any Manocept platform product candidate will ultimately achieve regulatory approval, or if approved, the extent to which it will achieve market acceptance.

#### NAV4694

NAV4694 is a Fluorine-18 labeled precision radiopharmaceutical candidate for use in the imaging and evaluation of patients with signs or symptoms of AD and potentially also MCI. 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 to date, NAV4694 appears to have better sensitivity and specificity in detecting beta-amyloid than other agents in development. Due to its high affinity for amyloid, improved contrast, and enhanced uptake in the amyloid-target regions of interest in the brain compared with low uptake in white matter background, better signal-to-noise ratios have been observed. Greater contrast may enable the ability to detect smaller amounts of

amyloid and earlier identification of disease, as well as the opportunity to detect smaller changes in amyloid levels and monitor disease progression over time.

NAV4694 has been studied in rigorous pre-clinical studies and clinical trials in humans. Clinical studies through Phase 3 have included subjects with MCI, suspected AD patients, and healthy volunteers. Results suggest that NAV4694 has the potential ability to image patients quickly and safely with high sensitivity and specificity. During 2013, we initiated a Phase 2b trial in subjects with MCI and a Phase 3 autopsy-based trial to support registration in the U.S. and the EU. During the first quarter of 2014, we reported data from a blinded read of over 160 cases in which NAV4694 showed sensitivity and specificity both in excess of 95%. Positive results were also reported from our Phase 2b trial in subjects with MCI, showing the agent's ability to identify beta-amyloid with a high confidence of diagnosis in these are early-stage patients for whom diagnostic uncertainty is often significant. These data build on prior work showing that NAV4694 can separate MCI patients with high beta amyloid who are likely to progress to AD from those who do not. To date, the product candidate appears to be safe and well-tolerated. We cannot assure you, however, that further clinical trials for this product will be successful, that the product 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.

Results from clinical trials to date 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 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, one of the most common forms of dementia after AD.

In December 2013, we announced that the first subject had been enrolled in a pivotal Phase 3 clinical trial to assess the safety and efficacy of NAV5001 as an aid in the differential diagnosis of Parkinsonian Syndromes from non-Parkinsonian tremor. This clinical study is focused on subjects with emerging symptoms in whom diagnostic uncertainty and unmet need are highest. Results from earlier trials using NAV5001 suggest that it may be an effective, well-tolerated imaging agent. The high affinity for DAT with resulting clear images can assist physicians in reaching an accurate diagnosis sooner, and the rapid kinetics with minimal time between injection and scanning and time in the SPECT scanner not only decrease patient exposure and but also facilitate increased efficiency with potential cost savings for the nuclear medicine facility. Reducing diagnostic uncertainty and error rates for patients with movement disorders who often exhibit similar clinical symptoms has the potential to afford great value, especially early in the initial clinical presentation, and may lead to improved clinical decision-making and patient management. We cannot assure you, however, that further clinical trials for this product will be successful, that the product will achieve regulatory approval, or if approved, that it will achieve market acceptance.

#### NAV1800

NAV1800 is intended to aid in identifying a primary tumor, ascertaining margins, or determining the extent and location of occult and metastatic tumor in patients with solid tumor cancers, such as colorectal cancer, ovarian cancer, prostate cancer, lung cancer and other cancers of epithelial origin. The detection of clinically occult tumor is intended to provide the surgeon with a more accurate assessment of the extent of disease, and therefore may impact the surgical and therapeutic management of the patient. Development to date has been focused on the radiolabeling of a monoclonal antibody that serves as the biologic targeting agent. The antibody localizes or binds to a tumor antigen called TAG-72 expressed on many solid tumor cancers.

In November 2013, we entered into a collaboration with investigators at the University of Alabama at Birmingham (UAB) on a potential clinical study to evaluate the safety and efficacy of NAV1800 in cancer patients. We have not yet initiated clinical activities under our collaboration with UAB as we continue to evaluate the technical, clinical and manufacturing parameters required for further exploitation. We cannot assure you that if further clinical trials for this product proceed, that they will be successful, that the product will achieve regulatory approval, or if approved, that it will achieve market acceptance.

## Outlook

Following the U.S. approval of Lymphoseek in March 2013, the Company undertook the initial stages of product launch in the U.S. with our commercialization partner, Cardinal Health, in May 2013. We began reporting revenue from Lymphoseek beginning in the second quarter of 2013, though revenue for the second quarter consisted primarily of inventory stocking of Cardinal Health's nuclear pharmacies. As insight into the sales process with Lymphoseek has grown over the initial quarters following launch, we announced our expectation for revenue to Navidea from Lymphoseek to be between \$5 million and \$6 million for 2014. We expect to update this guidance on a quarterly basis over the remainder of 2014 and are reiterating that guidance at this time. The Company currently believes Lymphoseek has the potential to achieve a market leadership position among lymphatic mapping agents in the U.S. by mid-2015.

Our operating expenses in recent years have been focused primarily on support of Lymphoseek, our Manocept platform, NAV4694 and NAV5001 product development, and to a lesser extent, on efforts to restart active development of NAV1800. We incurred approximately \$5.2 million and \$3.6 million in total on research and development activities during the three-month periods ended March 31, 2014 and 2013, respectively. Of the total amounts we have 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 out-of-pocket charges by program as follows:

Development Program	Three Months Ended	
	March 31,	
	2014	2013
Lymphoseek	\$625,583	\$785,495
Manocept Platform	167,013	—
NAV4694	1,618,128	781,453
NAV5001	519,158	137,963
NAV1800	27,865	50,000

Due to the advancement of our efforts with Lymphoseek, our Manocept platform, NAV4694, NAV5001, and NAV1800, we expect our total research and development expenses for 2014 to be in the range of approximately \$25 million to \$30 million. The levels of program expenditures will depend in part on efforts associated with advancing Lymphoseek and accelerating enrollment and other activities related to our NAV4694 program. In general, development expenses for Lymphoseek in 2014 are expected to decrease as compared to 2013; expenses in some other programs are anticipated to increase in 2014 over 2013, primarily driven by NAV4694, and to a lesser extent, Manocept. We expect expenses for NAV5001 to be largely steady and commensurate with our available resources. Expenses related to NAV1800 may increase in 2014 from 2013, but in a manner consistent with funding available under our National Institutes of Health (NIH) Small Business Innovation Research (SBIR) grant.

Lymphoseek was approved and indicated for use in lymphatic mapping in patients with breast cancer and melanoma by the FDA in March 2013. Although our marketing partner will bear the direct marketing, sales and distribution costs related to the sale of Lymphoseek, during 2014, we expect to incur ongoing costs to support product launch, general marketing and medical education-related and market outreach activities associated with Lymphoseek commercialization. We expect to incur additional development expenses related to supporting the MAA review of Lymphoseek in the EU and support the other product, regulatory, manufacturing and commercial activities related to the potential marketing registration and sale of Lymphoseek in other markets. Additionally, we anticipate that we will incur costs related to the FDA review and advancement of our two Lymphoseek sNDAs. We cannot assure you that Lymphoseek will achieve regulatory approval in the EU or any other market outside the U.S., or if approved in those markets, that it will achieve market acceptance in the U.S. or any other market.

We are currently evaluating existing and emerging data on the potential use of Manocept-related agents in the diagnosis and disease-staging of disorders in which macrophages are involved such as KS, RA, tuberculosis and other disease states, to define areas of focus, development pathways and partnering options to capitalize on the Manocept platform. In the near-term, our development efforts with respect to the Manocept platform will likely be limited to such evaluations. We will also be evaluating potential funding and other resources required for continued development, regulatory approval and commercialization of any Manocept platform product candidates that we identify for further development, and potential options for advancing development. We cannot assure you that further evaluation or development will be successful, that any Manocept platform product candidate will ultimately achieve regulatory approval, or if approved, the extent to which it will achieve market acceptance.

We expect to incur significant expenses for NAV4694 during 2014 related to ongoing Phase 2 clinical trials and a pivotal Phase 3 clinical trial in subjects with AD, as well as costs for manufacturing-related activities required prior to filing for regulatory clearance to market. We also expect to incur significant expenses for NAV5001 during 2014, primarily in support of our Phase 3 clinical trials, as well as for manufacturing-related activities required to support our clinical trial and registration efforts. During 2013, we were awarded two SBIR grants from the NIA in connection with our Phase 3 clinical programs for NAV4694, the first as an aid in the differential diagnosis of AD and the second as a diagnostic imaging agent that may aid physicians in identifying individuals with MCI who are at greatest risk of progressing to AD. These SBIR grants have the potential to provide up to \$1.8 million and \$2.3 million in support, respectively, if fully funded, through the conclusion of the Phase 3 clinical studies. Currently, neither NAV4694 nor NAV5001 is expected to contribute revenue to the Company until at least 2017. We cannot assure you that further clinical trials for these products will be successful, that the agents will ultimately achieve regulatory approval, or if approved, the extent to which they will achieve market acceptance.

We continue to evaluate potential business, clinical, manufacturing, development and regulatory pathways forward for the NAV1800 program. In the near-term, our development efforts related to NAV1800 will likely be limited to those which we are able to fund through external sources such as the SBIR grant from the NIH we were awarded in 2012. We cannot assure you that we will be able to complete satisfactory development arrangements or obtain incremental financing to fund the NAV1800 program and cannot guarantee that such arrangements could be obtained on a timely basis on terms acceptable to us, or at all. We also cannot assure you that further clinical development will be successful, that the agent will ultimately achieve regulatory approval, or if approved, that it will achieve market acceptance.

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

## Results of Operations

### Three Months Ended March 31, 2014 and 2013

**Net Sales and Margins.** Net sales of Lymphoseek realized by Navidea were \$627,000 during the first quarter of 2014. We did not record any sales revenue during the first quarter of 2013. Gross margins on net sales were 69% for the first quarter of 2014. Cost of goods sold included post-production testing activities required by regulatory authorities, which are charged as one-time period costs, and a royalty on net sales payable under our license agreement with UCSD.

**Grant Revenue.** During the first quarter of 2014, we recognized \$125,000 of grant revenue related to SBIR grants from the NIH supporting NAV4694 and NAV1800 development. We did not recognize any grant revenue during the first quarter of 2013.

**Research and Development Expenses.** Research and development expenses increased \$1.6 million, or 44%, to \$5.2 million during the first quarter of 2014 from \$3.6 million during the same period in 2013. The increase was primarily due to net increases in drug project expenses related to (i) increased NAV4694 development costs of \$837,000 including increased manufacturing-related activities coupled with increased clinical trial costs, (ii) increased NAV5001 development costs of \$381,000 including increased manufacturing-related activities coupled with increased clinical trial costs, and (iii) increased Manocept platform development costs of \$167,000; offset by (iv) decreased Lymphoseek development costs of \$160,000. The net increase in research and development expenses also included increased compensation including incentive-based awards and other related expenses of \$290,000 related to increased



headcount required for expanded development efforts over the prior year, as well as increased travel and other support costs.

**Selling, General and Administrative Expenses.** Selling, general and administrative expenses increased \$546,000, or 16%, to \$3.9 million during the first quarter of 2014 from \$3.4 million during the same period in 2013. The net increase was primarily due to increased medical education costs to support Lymphoseek of \$443,000 coupled with increased symposia and industry association support expenses, and facilities transition and other headcount-related costs, offset by decreased investor relations and out-of-pocket marketing costs related to the commercial launch of Lymphoseek.

**Other Income (Expense).** Other expense, net, was \$3.2 million during the first quarter of 2014 as compared to \$337,000 during the same period in 2013. During the first quarter of 2014, we recorded a \$2.6 million loss on the extinguishment of the GECC/MidCap Notes. Interest expense increased \$581,000 to \$944,000 during the first quarter of 2014 from \$363,000 for the same period in 2013, primarily due to the interest related to the GECC/MidCap and Oxford Notes in 2014, offset by interest related to the Hercules Note in 2013. Of this interest expense, \$242,000 and \$123,000 in the first quarter of 2014 and 2013, respectively, was non-cash in nature related to the amortization of debt issuance costs and non-cash debt discounts related to the

Oxford, GECC/MidCap, and Hercules Notes. For the first quarter of 2014, we recorded non-cash income of \$392,000 related to changes in the estimated fair value of financial instruments.

#### Liquidity and Capital Resources

Cash balances decreased to \$26.0 million at March 31, 2014 from \$32.9 million at December 31, 2013. The net decrease was primarily due to cash used to fund our operations, mainly for research and development activities, of \$9.2 million, and purchases of equipment of \$986,000, offset by a net increase of \$3.2 million related to the commencement of the Oxford Notes and the extinguishment of the GECC/Midcap Notes. The current ratio increased to 5.4:1 at March 31, 2014 from 3.3:1 at December 31, 2013.

Operating Activities. Cash used in operations increased \$1.8 million to \$9.2 million during the first quarter of 2014 compared to \$7.4 million used during the same period in 2013.

Accounts receivable decreased to \$587,000 at March 31, 2014 from \$1.2 million at December 31, 2013, primarily due to decreased amounts due from the landlord of our Dublin office space for tenant improvements, offset by increased receivables due from Cardinal Health resulting from the increase in sales of Lymphoseek.

Accounts payable remained steady at \$2.4 million at March 31, 2014 and December 31, 2013. Accrued liabilities and other current liabilities decreased to \$3.0 million at March 31, 2014 from \$4.8 million at December 31, 2013, primarily due to decreased accruals of NAV4694 development costs and net decreases in compensation-related accruals. Our payable and accrual balances will continue to fluctuate but will likely increase overall as we increase our level of commercial activity related to Lymphoseek, and development activity related to the Manocept platform, NAV4694, NAV5001, NAV1800, and other potential product candidates.

Investing Activities. Investing activities used \$993,000 during the first quarter of 2014 compared to using \$357,000 during the same period in 2013. Capital expenditures of \$986,000 during the first quarter of 2014 were primarily for leasehold improvements, office furniture and NAV4694 production equipment. Capital expenditures of \$355,000 during the first quarter of 2013 were primarily NAV4694 and Lymphoseek production equipment and software. We expect our overall capital expenditures for 2014 in total will be higher than in 2013.

Financing Activities. Financing activities provided \$3.2 million during the first quarter of 2014 compared to \$8.5 million provided during the same period in 2013. The \$3.2 million provided by financing activities in the first three months of 2014 consisted primarily of proceeds from the Oxford Notes of \$30.0 million, offset by payment of the principal and fees related to the extinguishment of the GECC/Midcap Notes of \$26.7 million. 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.

#### Oxford Debt

In March 2014, we executed a Loan and Security Agreement (the Oxford Loan Agreement) with Oxford Finance, LLC (Oxford), providing for a loan to the Company of \$30 million. Pursuant to the Oxford Loan Agreement, we issued Oxford: (1) Term Notes in the aggregate principal amount of \$30,000,000, bearing interest at 8.5% (the Oxford Notes), and (2) Series KK warrants to purchase an aggregate of 391,032 shares of our common stock at an exercise price of \$1.918 per share, expiring in March 2021 (the Series KK warrants). We will make monthly payments of interest only commencing on April 1, 2014, and continuing on the first calendar day of each successive month thereafter through and including the first calendar day of the month immediately preceding April 1, 2015 (the Amortization Date, which may be extended to April 1, 2016, and again to April 1, 2017, if the Company achieves certain milestones associated with the Company's Lymphoseek product). Commencing on the Amortization Date, and continuing on the first calendar day of each month thereafter, the Company will make consecutive equal monthly payments of principal and interest, in arrears, to the lenders then party to the Oxford Loan Agreement based on a repayment schedule of 48 months if the Amortization Date is April 1, 2015, 36 months if the Amortization Date is April 1, 2016, and 24 months if the Amortization Date is April 1, 2017. All unpaid principal, and accrued and unpaid interest, with respect to the Oxford Notes is due and payable in full on March 1, 2019. We will also make a final payment to the lenders in an aggregate amount equal to the original principal amount of the loan multiplied by 7.95% if the Amortization Date is April 1, 2015; 8.95% if the Amortization Date is extended to April 1, 2016; or 9.95% if the Amortization Date is extended to April 1, 2017. The Oxford Notes are 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 Oxford Loan Agreement requires that the Company adhere to certain affirmative and negative covenants, including, without limitation, financial reporting requirements and a prohibition against the incurrence of indebtedness, or creation of additional liens, other than as specifically permitted by the terms of the Oxford Loan Agreement. As of March 31, 2014, the outstanding principal balance of the Oxford Loan Agreement was \$30 million, and we were in compliance with all covenants of the Oxford Loan Agreement.

#### GECC/MidCap Debt

Also in March 2014, in connection with the consummation of the Oxford Loan Agreement, we repaid all amounts outstanding under the General Electric Capital Corporation (GECC) and MidCap Financial SBIC, LP (MidCap) Notes for a payoff amount of \$26.7 million, which included payments of \$500,000 as a pre-payment fee and \$1,000,000 as an end-of-term final payment fee.

#### Platinum Credit Facility

In March 2014, in connection with entering into the Oxford Loan Agreement, we entered into a second amendment to the Platinum-Montaur Life Sciences, LLC (Platinum) Loan Agreement (the Second Platinum Amendment). Concurrent with the execution of the Second Platinum Amendment, the Company delivered an Amended and Restated Promissory Note (the Second Amended Platinum Note) to Platinum, which amended and restated the First Amended Platinum Note. The Second Amended Platinum Note adjusted the interest rate to the greater of (i) the United States prime rate as reported in The Wall Street Journal plus 6.75%, (ii) 10.0%, and (iii) the highest rate of interest then payable by the Company pursuant to the Oxford Loan Agreement plus 0.125%. Navidea, Platinum, and Oxford also entered into a Subordination Agreement, providing for subordination of the Company's indebtedness under the Platinum Loan Agreement to the Company's indebtedness under the Oxford Loan Agreement, among other customary terms and conditions. As of March 31, 2014, the remaining outstanding principal balance of the Second Amended Platinum Note was approximately \$3.2 million, with \$31.8 million still currently available under the credit facility.

#### Series B Convertible Preferred Stock

During the three-month period ended March 31, 2014, Platinum converted 4,162 shares of their Series B Preferred Stock into 13,609,740 shares of our common stock under the terms of the Series B Preferred Stock. As of March 31, 2014, there are 3,403 shares of Series B Preferred Stock outstanding which are convertible into 11,127,810 shares of our common stock.

#### Summary

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

We believe that our current cash balance, our credit facility with Platinum, our projected revenue derived from U.S. sales of Lymphoseek, our ability to control expenses, the potential for partnership funding, the potential to access debt or royalty instruments, and the potential to access capital markets through our shelf registration, though we have no current intent to raise funds through approaching the equity capital markets, provide us with adequate financial resources to continue to fund our business plan for the foreseeable future. However, we cannot assure you that Lymphoseek will generate our expected levels of sales and cash flow. We will continue to evaluate our time lines, strategic needs, and balance sheet requirements. We cannot assure you that if we attempt to raise additional capital through debt, royalty, equity or otherwise, we will be successful in doing so on terms acceptable to the Company, or at all. We also cannot assure you that we will be able to gain access and/or be able to execute on securing new development opportunities, successfully obtain regulatory approval for and commercialize new products, achieve significant product revenues from our products, or achieve or sustain profitability in the future.

#### Recent Accounting Developments

There were no additional new accounting pronouncements adopted during the three months ended March 31, 2014 that had a material impact on our financial statements.

#### Critical Accounting Policies

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

**Revenue Recognition.** We currently generate revenue primarily from sales of Lymphoseek. Our standard shipping terms are FOB shipping point, and title and risk of loss passes to the customer upon delivery to a carrier for shipment from Cardinal Health's national distribution center to another point of destination. We generally recognize sales revenue related to sales of our products when the products are shipped. Our customers have no right to return products purchased in the ordinary course of business.

We earn additional revenues based on a percentage of the actual net revenues achieved by Cardinal Health on sales to end customers made during each fiscal year. The amount we charge Cardinal Health related to end customer sales of Lymphoseek are subject to a retroactive annual adjustment. To the extent that we can reasonably estimate the end-customer prices received by Cardinal Health, we record sales based upon these estimates at the time of sale. If we are unable to reasonably estimate end customer sales prices related to products sold, we record revenue related to these product sales at the minimum (i.e., floor) price provided for under our distribution agreement with Cardinal Health.

We generate additional revenue from grants to support various product development initiatives. We generally recognize grant revenue when expenses reimbursable under the grants have been incurred and payments under the grants become contractually due.

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, chemistry, manufacturing and control-related activities, and regulatory costs. R&D expenses are charged to operations as incurred. We review and accrue R&D expenses based on services performed and rely upon estimates of those costs applicable to the stage of completion of each project.

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

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

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

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

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

### Item 3. Quantitative and Qualitative Disclosures About Market Risk

**Interest Rate Risk.** As of March 31, 2014, our \$26.0 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.

We also have exposure to changes in interest rates on our variable-rate debt obligations. As of March 31, 2014, the interest rate on certain of our debt obligations was based on the U.S. prime rate. Based on the amount of our variable-rate borrowings at March 31, 2014, which totaled approximately \$3.2 million, an immediate one percentage point increase in the U.S. prime rate would increase our annual interest expense by approximately \$32,000. This estimate assumes that the amount of variable rate borrowings remains constant for an annual period and that the interest rate change occurs at the beginning of the period. Because our debt obligations are currently subject to the minimum interest rates defined in the loan agreements, a decrease in the U.S. prime rate would not affect our annual interest expense.

Foreign Currency Exchange Rate Risk. We do not currently have material foreign currency exposure related to our assets as the majority are denominated in U.S. currency and our foreign-currency based transaction exchange risk is not material. For the three-month periods ended March 31, 2014 and 2013, we recorded foreign currency transaction gains (losses) of approximately \$2,000 and \$(16,000), 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 our warrant liabilities is determined using various inputs and assumptions, the majority of which are defined and fixed by the warrant agreement, including the price of Company stock. As of March 31, 2014, we had approximately \$7.7 million of derivative liabilities recorded on our balance sheet related to outstanding Series JJ warrants. Due to the fixed inputs defined by the warrant agreement, a hypothetical 50% change in our stock price would have no effect on the value of our derivative liabilities.

#### 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, 2014. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive and principal financial officers, as appropriate, to allow timely decisions regarding required disclosure. Based on our evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of the end of the period covered by this report, our disclosure controls and procedures are adequately designed and are effective.

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

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

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

#### Changes in Control Over Financial Reporting

During the quarter ended March 31, 2014, 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 reported in the Company's Annual Report on Form 10-K for the year ended December 31, 2013, filed with the SEC on March 14, 2014.

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

(a) During the three-month period ended March 31, 2014, we issued 13,609,740 shares of our common stock to Platinum in exchange for 4,162 shares of our Series B Convertible Preferred Stock in connection with Platinum's exercise of its conversion option pursuant to the terms of our Series B Convertible Preferred Stock. The conversion terms for the issuances during the period was 3,270 shares of our common stock in exchange for each share of our Series B Convertible Preferred Stock. The issuances of these securities were exempt from registration under Section 3(a)(9) of the Securities Act.

(b) There were no repurchases of our common stock during the three-month period ended March 31, 2014.

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)  
May 9, 2014

By: /s/ Mark J. Pykett

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

By: /s/ Brent L. Larson

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

INDEX TO EXHIBITS

- 3.2 Amended and Restated By-Laws of Navidea Biopharmaceuticals, Inc. (as adopted November 7, 2013)\*
- 31.1 Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.\*
- 31.2 Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.\*
- 32.1 Certification of Chief Executive Officer of Periodic Financial Reports pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350.\*\*
- 32.2 Certification of Chief Financial Officer of Periodic Financial Reports pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350.\*\*
- 101.INS XBRL Instance Document\*
- 101.SCH XBRL Taxonomy Extension Schema Document\*
- 101.CAL XBRL Taxonomy Extension Calculation Linkbase Document\*
- 101.DEF XBRL Taxonomy Extension Definition Linkbase Document\*
- 101.LAB XBRL Taxonomy Extension Label Linkbase Document\*
- 101.PRE XBRL Taxonomy Extension Presentation Linkbase Document\*

\* Filed herewith.

\*\* Furnished herewith.