

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

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, 2013

or

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

For the transition period from _____ to

Commission File Number: 001-35076

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

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

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

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

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

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

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

Yes No

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

Yes 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 12b-2 of the Exchange 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: 119,577,859 shares of common stock, par value \$.001 per share (as of the close of business on May 3, 2013).

NAVIDEA BIOPHARMACEUTICALS, INC. and SUBSIDIARIES

Index

PART I – Financial Information

Item 1. Financial Statements	3
Consolidated Balance Sheets as of March 31, 2013 (unaudited) and December 31, 2012	3
Consolidated Statements of Operations for the Three-Month Periods Ended March 31, 2013 and 2012 (unaudited)	5
Consolidated Statement of Stockholders’ Deficit for the Three-Month Period Ended March 31, 2013 (unaudited)	6
Consolidated Statements of Cash Flows for the Three-Month Periods Ended March 31, 2013 and 2012 (unaudited)	7
Notes to the Consolidated Financial Statements (unaudited)	8
Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations	15
Forward-Looking Statements	15
The Company	15
Product Line Overview	16
Outlook	18
Results of Operations	20
Liquidity and Capital Resources	21
Recent Accounting Developments	23
Critical Accounting Policies	23
Item 3. Quantitative and Qualitative Disclosures About Market Risk	24
Item 4. Controls and Procedures	25

PART II – Other Information

Item 1A.	Risk Factors	27
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	27
Item 6.	Exhibits	28

PART I – FINANCIAL INFORMATION**Item 1. Financial Statements****Navidea Biopharmaceuticals, Inc. and Subsidiaries****Consolidated Balance Sheets**

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

Continued

Navidea Biopharmaceuticals, Inc. and Subsidiaries

Consolidated Balance Sheets, continued

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

See accompanying notes to consolidated financial statements

Navidea Biopharmaceuticals, Inc. and Subsidiaries

Consolidated Statements of Operations

(unaudited)

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

See accompanying notes to consolidated financial statements.

Navidea Biopharmaceuticals, Inc. and Subsidiaries

Consolidated Statement of Stockholders' Deficit

(unaudited)

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

See accompanying notes to consolidated financial statements.

Navidea Biopharmaceuticals, Inc. and Subsidiaries

Consolidated Statements of Cash Flows

(unaudited)

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

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

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

See accompanying notes to consolidated financial statements.

Notes to Consolidated Financial Statements

(unaudited)

1. Summary of Significant Accounting Policies

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

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

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

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

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

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

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

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

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

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