

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

FORM 8-K

CURRENT REPORT  
Pursuant to Section 13 or 15(d) of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported) May 2, 2012

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

Delaware (State or other jurisdiction of incorporation)	001-35076 (Commission File Number)	31-1080091 (IRS Employer Identification No.)
425 Metro Place North, Suite 450, Dublin, Ohio (Address of principal executive offices)		43017 (Zip Code)

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

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

**Item 2.02. Results of Operations and Financial Condition.**

On May 2, 2012, Navidea Biopharmaceuticals, Inc. (the “Company”) issued a press release regarding its consolidated financial results for the first quarter ended March 31, 2012. A copy of the Company’s May 2, 2012, press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information contained in Item 2.02 of this Current Report on Form 8-K, including exhibit 99.1 attached hereto, shall not be treated as “filed” for purposes of the Securities Exchange Act of 1934, as amended.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

*Exhibit  
Number*

*Exhibit Description*

99.1	Navidea Biopharmaceuticals, Inc. press release dated May 2, 2012, entitled “Navidea Biopharmaceuticals Announces First Quarter 2012 Results.”
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Statements contained or incorporated by reference in this Current Report on Form 8-K which relate to other than strictly historical facts, such as statements about the Company’s plans and strategies, expectations for future financial performance, new and existing products and technologies, and markets for the Company’s products, are forward-looking statements. The words “believe,” “expect,” “anticipate,” “estimate,” “project,” and similar expressions identify forward-looking statements that speak only as of the date hereof. Investors are cautioned that such statements involve risks and uncertainties that could cause actual results to differ materially from historical or anticipated results due to many factors including, but not limited to, the Company’s continuing operating losses, uncertainty of market acceptance, reliance on third party manufacturers, accumulated deficit, future capital needs, uncertainty of capital funding, dependence on limited product line and distribution channels, competition, limited marketing and manufacturing experience, and other risks detailed in the Company’s most recent Annual Report on Form 10-K and other filings with the United States Securities and Exchange Commission. The Company undertakes no obligation to publicly update or revise any forward-looking statements.

## 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 hereunto duly authorized.

Navidea Biopharmaceuticals, Inc.

Date: May 2, 2012

By: /s/ Brent L. Larson

Brent L. Larson, Senior Vice President and  
Chief Financial Officer



Press Release

**FOR IMMEDIATE RELEASE**

**Navidea Biopharmaceuticals Announces First Quarter 2012 Results**  
**– Business Update / Quarterly Conference Call Set for Tomorrow, May 3, 2012,**  
**at 8:30 am EDT –**

DUBLIN, OHIO – May 2, 2012 – Navidea Biopharmaceuticals, Inc. (NYSE Amex: NAVB), a specialty pharmaceutical company focused on precision diagnostic radiopharmaceuticals, today announced business highlights and consolidated results for the first quarter ended March 31, 2012.

**Financial Results and Outlook**

For the quarter ended March 31, 2012, Navidea reported a net loss attributable to common stockholders of \$7.0 million, or \$0.07 per share, compared with a net loss attributable to common stockholders of \$4.4 million, or \$0.05 per share, for the same period in 2011.

During the third quarter of 2011, the Company sold its neoprobe<sup>®</sup> GDS line of gamma detection device systems to a third party. As such, results of operations related to the GDS business reported previously in various individual financial statement line items (i.e., revenues, cost of sales and research and development expenses) have been reclassified to discontinued operations for all periods presented. Navidea non-GDS revenues for the quarters ended March 31, 2012 and 2011 relate to grants received in support of the Company's drug development activities. Grant revenues for the quarter ended March 31, 2012 were \$12,000 compared to \$336,000 for the same period in 2011. Costs related to these grants received in support of development activities are recorded in research and development expenses.

Research and development (R&D) expenses were \$3.9 million for the quarter ended March 31, 2012, compared to \$2.4 million for the same period in 2011. The increase in R&D expenses in 2012 was attributable to several primary factors including: (1) Lymphoseek<sup>®</sup> development costs increased \$306,000 as costs to support the New Drug Application (NDA) review more than offset decreases in clinical trial costs; (2) during the first quarter of 2012, the Company paid a \$500,000 license option fee related to [<sup>123</sup>I]-E-IACFT, a neuro-imaging agent to aid in the diagnosis of Parkinson's disease and movement disorders; and (3) Navidea incurred approximately \$700,000 in increased R&D costs related to a combination of out-of-pocket costs related to pipeline development projects, as well as increased headcount to support these development efforts.

Selling, general and administrative expenses were \$2.6 million for the quarter ended March 31, 2012, compared to \$2.9 million for the same period in 2011. The net decrease of \$300,000 between the two periods was primarily due to the fact that selling, general and administrative expenses in 2011 included approximately \$1.7 million in non-recurring charges related to the separation of the Company's former CEO that was partly offset in the first quarter of 2012 by approximately \$1.1 million in increased marketing and business development costs in preparation for the commercial launch of Lymphoseek and efforts to continue to build the Company's pipeline, coupled with approximately \$300,000 in increases in other general and administrative headcount and professional services costs.

As of March 31, 2012, Navidea had cash and cash equivalents totaling approximately \$21.9 million.

Brent Larson, Navidea Senior Vice President and CFO, said, "The notification in early April from the United States Food and Drug Administration (FDA) that the Lymphoseek Prescription Drug User Fee Act (PDUFA) date has been extended by 90 days to September 10, 2012 has not impacted our business plan objectives. We remain confident that our strong financial position and experience in program management provides us with the financial flexibility to reach the point of revenue generation from Lymphoseek and support program development and growth for 2012 and beyond."

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## NAVIDEA BIOPHARMACEUTICALS

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Dr. Mark Pykett, Navidea President and CEO, stated, "As we reported previously, we are confident that the clinical data generated for Lymphoseek to date support a clear safety and efficacy profile that we believe holds value for patients and their physicians. The updated chemistry, manufacturing and control (CMC) information we submitted on March 30, 2012, as requested by the Agency late in the NDA review, related to one of several drug analytical assays and was a request for more data on product manufacturing. It did not call into question Lymphoseek safety, efficacy, or clinical study design, nor was it related to comparisons with sulfur colloid or our ongoing Phase 3 study in head and neck cancer. We believe the NDA submission for Lymphoseek provides a robust portfolio of data and information supporting FDA approval of this product. Our focus continues to be on supporting the FDA review and preparing with our partner for anticipated U.S. market introduction of Lymphoseek."

First quarter business highlights include:

- **Changed corporate name to Navidea Biopharmaceuticals Inc.**, to best reflect pipeline and product offerings, began trading under the ticker symbol NAVB, and launched a new website, [www.navidea.com](http://www.navidea.com)
- Entered into an option agreement with Alseres Pharmaceuticals, Inc. to negotiate a license of [<sup>123</sup>I]-E-IACFT Injection, an Iodine-123 radiolabeled imaging agent being developed as an aid in the diagnosis of Parkinson's disease and other movement disorders
- Obtained positive guidance from the European Medicines Agency for Lymphoseek and announced our intent to file a Marketing Authorization Application in the EU by the end of 2012 based on already completed clinical trials and supplementary information
- Data on Lymphoseek and AZD4694 presented at major scientific and medical conference presentations:
  - o Presented data at Sentinel Node Oncology Foundation and Sentinel Lymph Node Working Group demonstrating a favorable comparison of Lymphoseek to Sulfur Colloid
  - o First experience data presented by MD Anderson Cancer Center demonstrates the utility, diagnostic predictive value, and safety of Lymphoseek for both preoperative lymphoscintigraphy and intraoperative localization in head and neck squamous cell cancer at the 2012 Society of Surgical Oncology Meeting
  - o Data on AZD4694 presented by the Banner Institute at the 6th Annual Human Amyloid Imaging Meeting describing the use of [<sup>18</sup>F] AZD4694 in the examination of fibrillar Aβ burden as an aid in the diagnosis of Alzheimer's Disease

"We continue to move forward to achieve our clinical and regulatory objectives. Our innovative precision diagnostics portfolio remains strong and we expect this will drive a number of potential value-enhancing events going forward," said Dr. Pykett. "We expect U.S. approval and commercial launch of Lymphoseek later this year, and are continuing the advancement of the global registration process for Lymphoseek and our important later-stage clinical pipeline of candidates."

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**NAVIDEA BIOPHARMACEUTICALS**

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**Conference Call Details**

Navidea's President and CEO, Dr. Mark Pykett, Executive Vice President and Chief Business Officer, Dr. Thomas Tulip, and Senior Vice President and CFO, Brent Larson, will provide a development and business update and will discuss the Company's financial results for the first quarter of 2012 during the conference call. The conference call can be accessed as follows:

CONFERENCE CALL INFORMATION			
TO PARTICIPATE LIVE:		TO LISTEN TO A REPLAY:	
Date:	May 3, 2012	Available until:	May 17, 2012
Time:	8:30 am EDT	Toll-free (U.S.) Dial in # :	(877) 660-6853
		International Dial in # :	(201) 612-7415
Toll-free (U.S.) Dial in # :	(877) 407-8033		
International Dial in # :	(201) 689-8033	Replay passcode:	
		Account #:	286
		Conference ID #:	393568

**About Navidea Biopharmaceuticals**

Navidea Biopharmaceuticals, Inc. (NYSE Amex: NAVB) is a biopharmaceutical company focused on the development and commercialization of precision diagnostics and radiopharmaceutical agents. Navidea is actively developing three radiopharmaceutical agent platforms – Lymphoseek®, AZD4694 and RIGScan™ – to help identify the presence and status of undetected disease and enable better diagnostic accuracy, clinical decision-making and ultimately patient care. Navidea's strategy is to deliver superior growth and shareholder return by bringing to market novel radiopharmaceutical agents and advancing the Company's pipeline through selective acquisitions, global partnering and commercialization efforts. For more information, please visit [www.navidea.com](http://www.navidea.com).

*The Private Securities Litigation Reform Act of 1995 (the Act) provides a safe harbor for forward-looking statements made by or on behalf of the Company. Statements in this news release, which relate to other than strictly historical facts, such as statements about the Company's plans and strategies, expectations for future financial performance, new and existing products and technologies, anticipated clinical and regulatory pathways, and markets for the Company's products are forward-looking statements within the meaning of the Act. The words "believe," "expect," "anticipate," "estimate," "project," and similar expressions identify forward-looking statements that speak only as of the date hereof. Investors are cautioned that such statements involve risks and uncertainties that could cause actual results to differ materially from historical or anticipated results due to many factors including, but not limited to, the Company's continuing operating losses, uncertainty of market acceptance of its products, reliance on third party manufacturers, accumulated deficit, future capital needs, uncertainty of capital funding, dependence on limited product line and distribution channels, competition, limited marketing and manufacturing experience, risks of development of new products, regulatory risks and other risks detailed in the Company's most recent Annual Report on Form 10-K and other Securities and Exchange Commission filings. The Company undertakes no obligation to publicly update or revise any forward-looking statements.*

**Contact:**

Navidea Biopharmaceuticals, Inc. – Brent Larson, Sr. VP & CFO – (614) 822-2330

- Financial Tables to follow -

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NAVIDEA BIOPHARMACEUTICALS, INC.  
CONDENSED CONSOLIDATED BALANCE SHEETS

	March 31, 2012 (unaudited)	December 31, 2011
Assets:		
Cash	\$ 21,904,068	\$ 28,644,004
Other current assets	1,606,852	1,402,517
Non-current assets	<u>1,217,981</u>	<u>1,147,399</u>
Total assets	<u>\$ 24,728,901</u>	<u>\$ 31,193,920</u>
Liabilities and stockholders' equity:		
Note payable, net of discount, current	\$ 1,661,681	\$ -
Derivative liabilities, current	753,014	568,930
Other current liabilities	2,502,890	2,779,540
Note payable, net of discount	4,848,621	6,456,388
Other liabilities	253,842	257,315
Stockholders' equity	<u>14,708,853</u>	<u>21,131,747</u>
Total liabilities and stockholders' equity	<u>\$ 24,728,901</u>	<u>\$ 31,193,920</u>

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CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended	
	March 31, 2012 <u>(unaudited)</u>	March 31, 2011 <u>(unaudited)</u>
Grant revenue	\$ 11,931	\$ 335,962
Operating expenses:		
Research and development	3,943,714	2,435,598
Selling, general and administrative	<u>2,574,630</u>	<u>2,901,707</u>
Total operating expenses	<u>6,518,344</u>	<u>5,337,305</u>
Loss from operations	<u>(6,506,413)</u>	<u>(5,001,343)</u>
Interest expense	(293,671)	(1,607)
Change in derivative liabilities	(184,084)	(953,789)
Other income, net	<u>4,479</u>	<u>2,806</u>
Loss from continuing operations	(6,979,689)	(5,953,933)
Discontinued operations	<u>(9,383)</u>	<u>1,531,804</u>
Net loss	(6,989,072)	(4,422,129)
Preferred stock dividends	<u>(25,000)</u>	<u>(25,000)</u>
Loss attributable to common stockholders	<u>\$ (7,014,072)</u>	<u>\$ (4,447,129)</u>
Loss per common share (basic and diluted):		
Continuing operations	\$ (0.07)	\$ (0.07)
Discontinued operations	\$ (0.00)	\$ 0.02
Attributable to common stockholders	\$ (0.07)	\$ (0.05)
Weighted average shares outstanding:		
Basic and diluted	94,074,918	85,416,015

*end*