

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 1, 2013

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

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

On May 1, 2013, Navidea Biopharmaceuticals, Inc. (the “Company”) issued a press release announcing the U.S. launch of Lymphoseek® (technetium Tc 99m tilmanocept) Injection for use in lymphatic mapping procedures that are performed to help in the diagnostic evaluation of potential cancer spread for patients with breast cancer and melanoma. Lymphoseek was approved by the U.S. Food and Drug Administration in March 2013. As part of the Company’s U.S. distribution partnership, Cardinal Health is responsible for the sale and distribution of Lymphoseek to health care professionals through its existing network of nuclear pharmacies. The Company is working closely with Cardinal Health in all commercial activities and medical education programs for Lymphoseek.

Lymphoseek has been priced at \$300 per patient procedure. The Company has been working to ensure fair and equitable reimbursement for lymphatic mapping procedures using Lymphoseek. In the case of Medicare, the Company believes these procedures are currently reimbursable under established codes, and expects to apply for and receive a unique pass-through code for Lymphoseek within a few months. The Company and Cardinal Health will provide information and support to providers and payers to ensure that they can secure formulary status and appropriate payment.

A copy of the complete text of the Company’s May 1, 2013, press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

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, anticipated clinical and regulatory pathways 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 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

*Exhibit
Number*

Exhibit Description

99.1	Navidea Biopharmaceuticals, Inc. press release, dated May 1, 2013, entitled “Navidea Biopharmaceuticals Announces the U.S. Launch of Lymphoseek.”
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SIGNATURES

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

Navidea Biopharmaceuticals, Inc.

Date: May 1, 2013

By: /s/ Brent L. Larson

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



Press Release

FOR IMMEDIATE RELEASE

Navidea Biopharmaceuticals Announces the U.S. Launch of Lymphoseek®

- First new lymphatic mapping drug approved in more than 30 years -

DUBLIN, OHIO – May 1, 2013 - Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB), a biopharmaceutical company focused on the development and commercialization of precision diagnostic radiopharmaceuticals, today announced the U.S. launch of *Lymphoseek*® (*technetium Tc 99m tilmanocept*) Injection for use in lymphatic mapping procedures that are performed to help in the diagnostic evaluation of potential cancer spread for patients with breast cancer and melanoma. Lymphoseek was approved by the U.S. Food and Drug Administration (FDA) in March 2013.

As part of Navidea's U.S. distribution partnership, Cardinal Health is responsible for the sale and distribution of Lymphoseek to health care professionals through its existing network of nuclear pharmacies. Navidea is working closely with the company in all commercial activities and medical education programs for Lymphoseek.

"Commercialization of Lymphoseek in the U.S. marks a pivotal milestone for Navidea, and we are pleased to deliver this innovative diagnostic imaging agent to patients with breast cancer and melanoma, as we help advance the field of precision diagnostics," said Dr. Mark Pykett, Navidea's President and CEO. "With Cardinal Health's extensive reach and pre-eminent radiopharmacy network, combined with our own medical education activities now underway to engage target physician groups, we expect to begin driving optimal adoption of Lymphoseek throughout the U.S."

"We are very enthusiastic about exclusively supplying Lymphoseek through our more than 140 U.S. nuclear pharmacies at a time when lymphatic mapping continues to grow in importance for the diagnostic evaluation of cancer patients," said Sandra Wisniewski, Vice President of Marketing and Business Development for Cardinal Health Nuclear Pharmacy Services. "Through our collaborative efforts with Navidea, we have completed a comprehensive range of training and education programs and have a full portfolio of commercial tools to support a successful Lymphoseek commercialization."

Lymphoseek has been priced at \$300 per patient procedure. Navidea has been working to ensure fair and equitable reimbursement for lymphatic mapping procedures using Lymphoseek. In the case of Medicare, Navidea believes these procedures are currently reimbursable under established codes, and expects to apply for and receive a unique pass-through code for Lymphoseek within a few months. Navidea and Cardinal Health will provide information and support to providers and payers to ensure that they can secure formulary status and appropriate payment.

According to the American Cancer Society, approximately 232,000 new cases of breast cancer and 77,000 new cases of melanoma are expected to be diagnosed in the United States in 2013. One of the procedures used by physicians to help in the diagnostic evaluation of breast cancer and melanoma is lymphatic mapping. Lymphatic mapping is a widely used procedure in which lymph nodes that may contain tumor metastases are identified and biopsied to determine if cancer has spread beyond the primary tumor. Navidea estimates that lymphatic mapping is utilized in approximately 70% of these patients each year in the United States.

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Conference Call for Investors

Navidea Biopharmaceuticals will host a conference call for investors, today at 8:30 a.m. EDT to discuss the Lymphoseek launch. Conference call dial-in information is included below.

Conference Call Information			
TO PARTICIPATE LIVE:		TO LISTEN TO A REPLAY:	
Date:	May 1, 2013	Available until:	May 15, 2013
Time:	8:30 a.m. EDT	Toll-free (U.S.) Dial in # :	(877) 660-6853
		International Dial in # :	(201) 612-7415
Toll-free (U.S.) Dial in # :	(877) 407-8031		
International Dial in # :	(201) 689-8031	Replay passcode:	
		Account #:	268
		Conference ID #:	413373

About Lymphoseek®

Lymphoseek® (technetium Tc 99m tilmanocept) Injection is a novel, receptor-targeted, small-molecule radiopharmaceutical used in lymphatic mapping procedures that are performed to help in the diagnostic evaluation of potential cancer spread for patients with breast cancer and melanoma. Lymphoseek is designed to identify the lymph nodes that drain from a primary tumor, which have the highest probability of harboring cancer. Lymphoseek was approved by the U.S. Food and Drug Administration in March, 2013 for use in lymphatic mapping to assist in the localization of lymph nodes draining a primary tumor in patients with breast cancer or melanoma. The Company anticipates continuing development of Lymphoseek into other solid tumor areas that may include head and neck cancers, prostate cancer, thyroid cancer, lung/bronchus cancers, colorectal cancer and others.

Accurate diagnostic evaluation of cancer is critical, as it guides therapy decisions and determines patient prognosis and risk of recurrence. According to the American Cancer Society, approximately 232,000 new cases of breast cancer, 77,000 new cases of melanoma and 67,000 new cases of head and neck/oral cancer are expected to be diagnosed in the United States in 2013.

Indication and Important Safety Information About Lymphoseek

Indication

Lymphoseek (technetium Tc 99m tilmanocept) Injection is a lymphatic mapping agent indicated for use with a hand-held gamma counter to assist in the localization of lymph nodes draining a primary tumor site in patients with breast cancer or melanoma.

Important Safety Information

In clinical trials with Lymphoseek, no serious hypersensitivity reactions were reported, however Lymphoseek may pose a risk of such reactions due to its chemical similarity to dextran. Serious hypersensitivity reactions have been associated with dextran and modified forms of dextran (such as iron dextran drugs).

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Prior to the administration of Lymphoseek, patients should be asked about previous hypersensitivity reactions to drugs, in particular dextran and modified forms of dextran. Resuscitation equipment and trained personnel should be available at the time of Lymphoseek administration, and patients observed for signs or symptoms of hypersensitivity following injection.

The most common adverse reactions are injection site irritation and/or pain (<1%).

**FULL LYMPHOSEEK PRESCRIBING INFORMATION CAN BE FOUND AT:
WWW.LYMPHOSEEK.COM**

About Navidea Biopharmaceuticals, Inc.

Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB) is a biopharmaceutical company focused on the development and commercialization of precision diagnostics and radiopharmaceutical agents. Navidea is actively developing four radiopharmaceutical agent platforms – Lymphoseek®, NAV4694, NAV5001 and RIGScan™ – to help identify the sites and pathways 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.

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 – Brent Larson, Sr. VP & CFO – (614) 822-2330
Investor Relations – Stern Investor Relations, Inc. Beth DelGiaccio – (212) 362-1200

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