

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) October 15, 2014

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>5600 Blazer Parkway, Suite 200, 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 October 15, 2014, Navidea Biopharmaceuticals, Inc. (the “Company”) issued a press release announcing that the U.S. Food and Drug Administration (FDA) has approved the Supplemental New Drug Application (sNDA) for the expanded use of Lymphoseek[®] (technetium Tc 99m tilmanocept) injection for lymphatic mapping in additional types of solid tumors and adding Sentinel Lymph Node detection for breast cancer and melanoma to the approved indications. A copy of the Company’s October 15, 2014, press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

*Exhibit
Number*

Exhibit Description

99.1	Navidea Biopharmaceuticals, Inc. press release dated October 15, 2014, entitled “FDA Approves Expanded Use of Navidea’s Lymphoseek [®] for Lymphatic Mapping in Solid Tumors.”
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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: October 16, 2014

By: /s/ Brent L. Larson
Brent L. Larson, Executive Vice President and
Chief Financial Officer



Press Release

FOR IMMEDIATE RELEASE

FDA Approves Expanded Use of Navidea's Lymphoseek[®] for Lymphatic Mapping in Solid Tumors

- Lymphoseek[®] (technetium Tc 99m tilmanocept) Injection Use for Sentinel Lymph Node detection also expanded to include Breast Cancer and Melanoma -

- Expanded Lymphoseek indication increases the addressable market with the potential to benefit up to 1.2 million solid tumor patients in U.S. annually -

- Company to Host Conference Call on Wednesday, October 15, 2014, 8:30 a.m. EDT -

DUBLIN OHIO, October 15, 2014 — Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB), a biopharmaceutical company focused on precision diagnostic radiopharmaceuticals, today announced that the U.S. Food and Drug Administration (FDA) has approved the Supplemental New Drug Application (sNDA) for the expanded use of Lymphoseek[®] (technetium Tc 99m tilmanocept) injection for lymphatic mapping in solid tumors and adding Sentinel Lymph Node detection for breast cancer and melanoma to the approved indications. Lymphoseek is now indicated for:

- Lymphatic mapping using a handheld gamma counter to locate lymph nodes draining a primary tumor site in patients with solid tumors for which this procedure is a component of intraoperative management
- Guiding Sentinel Lymph Node Biopsy (SLNB) using a handheld gamma counter in patients with clinically node negative squamous cell carcinoma (SCC) of the oral cavity, breast cancer or melanoma.

The FDA also allowed expanded utilization of Lymphoseek with or without scintigraphic imaging, known as lymphoscintigraphy, to enable pre-operative imaging and mapping of lymph nodes to facilitate node localization during surgical procedures. Lymphoseek is the first and only FDA-approved radiopharmaceutical agent for sentinel lymph node detection, is the only FDA-approved agent for lymphatic mapping of solid tumors, and will be immediately available using existing reimbursement codes for this expanded population of cancer patients.

“Lymphoseek is now the only agent approved by the FDA for lymphatic mapping across solid tumors when used as a component of surgical management. This significantly expands the potential market for Lymphoseek and materially enhances the Company’s ability to promote the use of Lymphoseek in solid tumor cancers where assessment of lymphatic involvement is critical to properly staging the disease, especially colorectal, gynecological, lung and prostate cancers,” said Michael Goldberg, M.D., Interim Chief Executive Officer. “We are highly encouraged by the expanded FDA approval and believe that Lymphoseek now has the potential to become a standard-of-care in lymphatic mapping and sentinel lymph node biopsy for the staging and prognosis of upwards of 1.2 million patients diagnosed with solid tumors annually in the U.S. We are eager to discuss the new label with surgeons and oncologists whose patients should benefit from the improved data resulting from better utilization of lymphatic mapping and Sentinel Lymph Node Biopsy procedures.”

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“Based on our clinical experience in melanoma and head and neck cancers, Lymphoseek appears to be an effective agent for cancer staging to guide pre- and intra-operative patient management and post-surgical treatment thereby avoiding unnecessary surgical interventions, reducing surgical time and limiting potential complications with associated morbidity,” commented Dr. Stephen Y. Lai, M.D., Ph.D., FACS, Associate Professor, Department of Head and Neck Surgery, The University of Texas MD Anderson Cancer Center. “The ability of Lymphoseek to accurately identify sentinel lymph nodes in patients, demonstrated in clinical evidence from more than 500 patients, may not only improve diagnostic accuracy, but also enable more efficient and appropriate patient care and provide us with greater precision during surgery to detect lymph nodes with the highest likelihood of harboring tumor metastases.”

“The success of lymphatic mapping and sentinel lymph node biopsy is dependent upon a radiopharmaceutical’s ability to concentrate in the lymph nodes most likely to contain cancer,” said H. William Strauss, M.D., Attending Physician Emeritus, Molecular Imaging and Therapy Service at Memorial Sloan-Kettering Cancer Center. “Lymphoseek, with its specifically-designed ability to target molecular markers in tumor-draining lymph nodes, has shown through clinical studies in breast cancer, melanoma and certain head and neck cancers, to possess a high degree of sensitivity and accuracy. Based on the reliable performance of Lymphoseek as demonstrated in these tumor-types, this approval opens up potential diagnostic imaging opportunities broadly across all forms of solid tumors.”

The expanded approval is supported by data from Navidea’s combined analysis of Lymphoseek’s pivotal prospective Phase 3 data in melanoma, breast cancer, and certain head and neck cancers from more than 500 subjects. An integrated analysis of data from all three studies showed positive diagnostic performance of Lymphoseek across the solid tumor types studied. The findings indicate that Lymphoseek accurately identified lymph nodes for assessment in the trial subjects, and is likely to be predictive of overall node pathology status. To date, no clinically significant drug-related adverse reactions have been reported. Lymphoseek has no contraindications and the most common adverse reactions were injection site irritation and/or pain (<1%).

In the approval action letter, the FDA also outlined a post-marketing requirement for initiation of a pediatric study in solid tumor cancer with a target date for submission in 2018.

Conference Call Details

Navidea will host a conference call with the investment community to discuss the sNDA scheduled for Wednesday, October 15, 2014 at 8:30 a.m. EDT. Investors and the public are invited to access the live webcast through the link below. Participants who would like to ask questions during the question and answer session following the presentation must participate by telephone also. Participants are encouraged to log-in and/or dial-in fifteen minutes before the conference call begins. The webcast replay is expected to be available on our investor website, <http://ir.navidea.com>, approximately two to four hours after the live event.

Event:	Navidea Biopharmaceuticals sNDA Approval Call
Date/Time:	Wednesday, October 15, 2014 at 8:30 a.m. EDT
Webcast Link:	http://public.viavid.com/index.php?id=111146
Dial-in Number – US:	1-877-407-0789
Dial in Number – Int’l:	1-201-689-8562
Replay	A webcast replay will be available on the Investor Relations section of our website at http://ir.navidea.com .

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About Lymphoseek

Lymphoseek® (technetium Tc 99m tilmanocept) injection is the first and only FDA-approved receptor-targeted lymphatic mapping agent. It is a novel, receptor-targeted, small-molecule radiopharmaceutical used in the evaluation of lymphatic basins that may have cancer involvement in patients. Lymphoseek is designed for the precise identification of lymph nodes that drain from a primary tumor, which have the highest probability of harboring cancer. Lymphoseek is approved by the U.S. Food and Drug Administration (FDA) for use in solid tumor cancers where lymphatic mapping is a component of surgical management and for guiding sentinel lymph node biopsy in patients with clinically node negative breast cancer, melanoma or squamous cell carcinoma of the oral cavity. Lymphoseek has also been recommended by CHMP for European approval in sentinel lymph node detection for melanoma, breast cancer or squamous cell carcinoma of the oral cavity.

Accurate diagnostic evaluation of cancer is critical, as it guides therapy decisions and determines patient prognosis and risk of recurrence. Overall in the U.S., solid tumor cancers may represent up to 1.2 million cases per year. The sentinel node label in the U.S. and Europe may address approximately 235,000 new cases of breast cancer, 76,000 new cases of melanoma and 45,000 new cases of head and neck/oral cancer in the U.S., and approximately 367,000 new cases of breast cancer, 83,000 new cases of melanoma and 55,000 new cases of head and neck/oral cancer diagnosed in Europe annually.

Lymphoseek Indication and Important Safety Information

Lymphoseek is a radioactive diagnostic agent indicated with or without scintigraphic imaging for:

- Lymphatic mapping using a handheld gamma counter to locate lymph nodes draining a primary tumor site in patients with solid tumors for which this procedure is a component of intraoperative management.
- Guiding sentinel lymph node biopsy using a handheld gamma counter in patients with clinically node negative squamous cell carcinoma of the oral cavity, 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).

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.

Any radiation-emitting product may increase the risk for cancer. Adhere to dose recommendations and ensure safe handling to minimize the risk for excessive radiation exposure to patients or health care workers.

In clinical trials, no patients experienced serious adverse reactions and the most common adverse reactions were injection site irritation and/or pain (<1%).

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

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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 developing multiple precision diagnostic products and platforms including Manocept™, NAV4694, NAV5001, and NAV1800 (RIGScan™), to help identify the sites and pathways of undetected disease and enable better diagnostic accuracy, clinical decision-making and, ultimately, patient care. Lymphoseek® (technetium Tc 99m tilmanocept) injection, Navidea's first commercial product from the Manocept platform, was approved by the FDA in March 2013. 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.

Source: Navidea Biopharmaceuticals, Inc.

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