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) September 26, 2014

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

Delaware	001-35076	31-1080091
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

5600 Blazer Parkway, Suite 200, Dublin, Ohio	43017
(Address of principal executive offices)	(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 8.01. Other Events.

On September 26, 2014, Navidea Biopharmaceuticals, Inc. (the "Company") issued a press release announcing that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency has recommended approval of Lymphoseek® for use in sentinel node detection for melanoma, breast, and certain head and neck cancers. A copy of the Company's September 26, 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 September 26, 2014, entitled "Navidea's Lymphoseek® Recommended by CHMP for European Approval in Sentinel Lymph Node Detection for Melanoma, Breast, and Certain Head and Neck Cancers."

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 1, 2014

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

Exhibit 99.1

Navidea BIOPHARMACEUTICALS Press Release

FOR IMMEDIATE RELEASE

Navidea's Lymphoseek® Recommended by CHMP for European Approval in Sentinel Lymph Node Detection for Melanoma, Breast and Certain Head and Neck Cancers

- *Following European Commission authorization, Lymphoseek (technetium Tc 99m tilmanocept) Injection will be the first approved Sentinel Lymph Node detection agent in the EU -*

DUBLIN OHIO September 26, 2014 -- Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB) has announced that that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion recommending the granting of marketing authorization for Lymphoseek® 250 micrograms kit for radiopharmaceutical preparation (tilmanocept) in the European Union (EU). The recommendation is for Lymphoseek use in imaging and intraoperative detection of sentinel lymph nodes draining a primary tumor in adult patients with breast cancer, melanoma, or head and neck oral cavity squamous cell carcinoma.

The CHMP's positive recommendation will be reviewed by the European Commission, which has the authority to approve medicinal products for use in the 28 countries of the European Union and generally follows the recommendations of the CHMP. Navidea expects the European Commission to issue its final decision on the marketing authorization for Lymphoseek later this year.

"This positive CHMP opinion moves Lymphoseek closer to becoming the first and only sentinel lymph node detection agent approved in all 28 member countries of European Union," said Michael Goldberg, M.D., Interim CEO of Navidea. "We believe Lymphoseek is differentiated in its ability to reliably and accurately locate sentinel lymph nodes draining a tumor, to help more effectively stage cancer and inform post-surgical treatment, and to decrease patient morbidity. We are increasingly excited by the global opportunity for Lymphoseek as we build upon our approval in the U.S. and prepare to make the product available next year to physicians in Europe looking to provide the best care for their patients."

"Current medical practices for head and neck cancers call for removal of large numbers of lymph nodes, lymph node dissection, even in patients without proven lymph node metastasis," said Professor Remco de Bree, M.D., Ph.D., Department of Otolaryngology-Head and Neck Surgery, VU University Medical Center, Amsterdam, The Netherlands. "Using the common practice of elective treatment of the neck, large numbers of patients undergo unnecessary extensive surgical procedures, which are associated with the risk of decreased shoulder function, decreased quality of life and increased costs. The practice of Sentinel Lymph Node Biopsy (SLNB) may offer a less invasive and equally predictive alternative for patient staging and directing adequate treatment of the neck. We welcome the addition of Lymphoseek in Europe as an approved sentinel lymph node detection agent with the potential to offer surgeons the ability to reliably and accurately guide SLNB procedures."

The opinion of the CHMP was based on positive and consistent results from Lymphoseek's three pivotal prospective Phase 3 studies in melanoma, breast cancer, and certain head and neck cancers and included associated analysis of the combined data from more than 500 subjects. All three studies showed positive diagnostic performance of Lymphoseek across the solid tumor types studied. 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%).

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Lymphoseek is approved in the U.S. by the U.S. Food and Drug Administration (FDA) for use in lymphatic mapping to assist in the detection of tumor-draining lymph nodes in patients with breast cancer or melanoma and for use in guiding sentinel lymph node biopsy in certain oral cancer patients. Lymphoseek is also the subject of a supplemental New Drug Application (sNDA) currently under review by the FDA, related to broader and more flexible utilization in lymphatic mapping procedures.

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 with breast cancer, melanoma and head and neck cancer patients with oral cavity carcinoma. 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 lymphatic mapping to assist in the localization of lymph nodes draining a primary tumor in patients with breast cancer or melanoma and for use in guiding sentinel lymph node biopsy in head and neck cancer patients with squamous cell carcinoma of the oral cavity. The Company anticipates continuing development of Lymphoseek into other solid tumor areas.

Accurate diagnostic evaluation of cancer is critical, as it guides therapy decisions and determines patient prognosis and risk of recurrence. According to publicly available information, 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 are expected to be diagnosed in the United States in 2014, 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 in the United States

Lymphoseek (technetium Tc 99m tilmanocept) Injection is indicated, using a hand-held gamma counter, for:

- Lymphatic mapping to assist in the localization of lymph nodes draining a primary tumor site in patients with breast cancer or melanoma;
- Guiding sentinel lymph node biopsy, in patients with clinically node negative squamous cell carcinoma (SCC) of the oral cavity.

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.

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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

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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Brent Larson, 614-822-2330
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or
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Associate Director, Corporate Communications

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