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 18, 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 18, 2014, Navidea Biopharmaceuticals, Inc. (the "Company") issued a press release announcing its receipt of Orphan Drug Designation from the U.S. Food and Drug Administration for use of Lymphoseek® in head and neck cancers. A copy of the Company's September 18, 2014, press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

On September 23, 2014, the Company issued a press release announcing a $1.67 million Fast Track NIH SBIR grant for evaluation of Lymphoseek® in cervical cancer. A copy of the Company's September 23, 2014, press release is furnished as Exhibit 99.2 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 18, 2014, entitled "Navidea Receives Orphan Drug Designation from FDA for Use of Lymphoseek® in Head and Neck Cancers."
99.2	Navidea Biopharmaceuticals, Inc. press release dated September 23, 2014, entitled "Navidea Awarded $1.67M Fast Track NIH SBIR Grant for Evaluation of Lymphoseek® in Cervical Cancer."

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: September 24, 2014

By: /s/ Brent L. Larson

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

Exhibit 99.1

Press Release

FOR IMMEDIATE RELEASE

Navidea Receives Orphan Drug Designation from FDA for Use of Lymphoseek ® in Head and Neck Cancers

DUBLIN OHIO September 18, 2014 — Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB) today announced that Lymphoseek ® (technetium Tc 99m tilmanocept) Injection has been granted Orphan Drug Designation by the U.S. Food & Drug Administration (FDA) for use in sentinel lymph node detection in patients with cancer of the head and neck. The designation is based upon an estimated 40,000 procedures being performed in this patient population. The FDA Office of Orphan Products Development (OOPD) mission is to advance the evaluation and development of products (drugs, biologics, devices, or medical foods) that demonstrate promise for the diagnosis and/or treatment of rare diseases or conditions.

“This Orphan Drug designation provides further validation of Lymphoseek for sentinel lymph node detection, underscores the need for new innovations in the treatment of patients with head and neck cancer, and, importantly strengthens Navidea’s competitive position by providing seven years of market exclusivity in this indication," said Michael Goldberg M.D., Navidea Interim CEO. "This decision follows the FDA Fast Track designation, Priority Review and subsequent sNDA approval of Lymphoseek for guiding sentinel lymph node biopsy in head and neck cancer patients with squamous cell carcinoma of the oral cavity.”

The FDA Orphan Drug Designation program provides a special status to drugs and biologics intended to treat, diagnose or prevent rare, or ‘orphan’, diseases and disorders, defined as affecting fewer than 200,000 people in the U.S. This designation provides for a seven-year marketing exclusivity period against competition in head and neck cancers as well as certain incentives, including federal grants, tax credits and a waiver of PDUFA filing fees, which qualifies the Company to request a refund of previously paid filing fees of up to $1.1 million.

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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 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.

Lymphoseek Indication and Important Safety Information

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.

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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

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.
Navidea Biopharmaceuticals
Brent Larson, 614-822-2330
Executive VP & CFO
or
Sharon Correia, 978-655-2686
Associate Director, Corporate Communications

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Exhibit 99.2

FOR IMMEDIATE RELEASE

Navidea Awarded $1.67M Fast Track NIH SBIR Grant for Evaluation of Lymphoseek ® in Cervical Cancer

DUBLIN OHIO, September 23, 2014 — Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB), today announced the receipt of an initial notice of award for a Fast Track Small Business Innovation Research (SBIR) grant providing for up to $1.67 million from the National Cancer Institute (NCI), National Institutes of Health (NIH), to fund evaluation of Lymphoseek® (technetium Tc 99m tilmanocept) Injection in women with cervical cancer. The multicenter, clinical study in patients with early cervical cancer will seek to assess and provide data in support of the use of Lymphoseek in sentinel lymph node biopsy (SLNB) procedures which identify and evaluate the lymph nodes most likely to harbor additional cancer.

The SBIR grant is awarded in two parts with the potential for total grant money up to a total of $1.67 million over two and a half years. The first six-month funding segment of $165,917, which has already been awarded, is expected to enable Navidea to identify and qualify trial sites and secure necessary contracts and Institutional Review Board (IRB) approvals. The second funding segment could provide for up to an additional $1.5 million to be used to accrue participants; perform the sentinel lymph node (SLN) procedures and pathology evaluations; and perform data analyses to confirm the safety and effectiveness of Lymphoseek.

“UC San Diego Moores Cancer Center played a key role in tilmanocept's Phase1-3 clinical evaluation for sentinel lymph node assessment in melanoma, breast cancer and squamous cell carcinoma of the head and neck," said Michael T. McHale, M.D., Associate Professor, Fellowship Director, Division of Gynecologic Oncology, UC San Diego Moores Cancer Center. "There is currently a growing focus on sentinel lymph node biopsy (SLNB) procedures in gynecologic cancers. We are pleased to participate in this important study which will evaluate and compare the abilities of tilmanocept and an alternative detection agent to identify SLNs during cervical cancer surgery. If successful, this study could potentially advance the use of SLNB procedures in cervical cancer.”

“We appreciate NCI’s support as we seek to further broaden the Lymphoseek label which is currently indicated for use in lymphatic mapping for breast cancer and melanoma, and to guide Sentinel Lymph Node Biopsy in certain head and neck cancers," said Frederick O. Cope, Ph.D., F.A.C.N., C.N.S Senior Vice President and Chief Scientific Officer of Navidea. "The current standard of care in cervical cancer surgery is to remove in excess of 20 lymph nodes which often leads to more extensive, complex and costly surgical procedures as well as potentially to serious post-surgical complications and morbidity. By accurately and reliably identifying the first lymph nodes draining a tumor, Lymphoseek may provide surgeons important disease staging information that can guide treatment decisions and improve patient outcomes.”

“This study is an excellent example of how we intend to support the expanded use of Lymphoseek to help patients afflicted with other solid tumor areas,” said Michael Goldberg, M.D., Navidea Interim CEO. “With 3-4 million new solid tumors each year in the US and Europe, this and other studies will help establish and standardize surgical methods and SLN procedures with the goal to establish Lymphoseek as a new standard of care for guiding patient treatment.”

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This study is designed as a multicenter, open-label, within-patient comparative study of Lymphoseek and an alternative lymphatic mapping agent referred to as vital blue dye for detection of lymph nodes in patients with cervical cancer. The study, using lymphatic mapping and SLN biopsy procedures, will compare the abilities of Lymphoseek and the alternative agent to identify SLNs during cervical cancer surgery. Additionally, the sentinel node pathology will be contrasted between agents and between the pathology of other nodes that may be removed during the procedure (non-sentinel nodes). The study is expected to involve 40 patients and last 1.5 years.

About Cervical Cancer
Cervical cancer is usually a slow-growing cancer that affects ~12,000 new patients each year in the U.S. Worldwide, the World Health Organization notes that cervical cancer is both the fourth most common cause of cancer and the fourth most common cause of death from cancer in women. Globally in 2012, it was estimated that there were 528,000 new cases of cervical cancer, and 266,000 deaths.

About Sentinel Lymph Node Biopsy Approach
Cancer patients can frequently be cured of cancer by surgeries that remove their tumors. To be successful, these surgeries must remove all of a patient's cancer. Residual tumor tissue in patients after surgery can result in potentially life threatening disease recurrences. It is very common that the first places to which a cancer may spread (metastasize) beyond the primary tumor are to lymph nodes adjacent to the tumor bed. During surgery in many types of cancer, the current standard of care has been to remove at least 20 and as many as 100 lymph nodes for examination for the presence of cancer. However, wholesale lymph node removal frequently results in longer and more painful recoveries and causes patients to develop lymphedema, a serious post-surgical complication among other morbidities and may also add dramatically to the cost and complexity of surgeries.

These problems have led to growing acceptance of sentinel lymph node biopsy (SLNB) as an alternative approach to full node dissections. SLNs are those lymph nodes that are first encountered by the lymphatic drainage away from a tumor. During an SLNB, only the SLNs are removed and evaluated for the presence of cancer. When SLNs do not contain cancer, which is very frequently the case, there is no need to perform a lymphadenectomy, sparing patients of the consequences of these procedures. In cancers such as cervical cancer there remains a need for a safe and effective mapping agent to reliably identify SLNs in all lymphatic drainage basins.

About Lymphoseek®
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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.

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