**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) February 17, 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.) |

| 425 Metro Place North, Suite 450, 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 5.02. Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.**

Effective February 17, 2014, Navidea Biopharmaceuticals, Inc. (the "Company") appointed Perry A. Karsen to serve on its Board of Directors (the "Board"). The appointment of Mr. Karsen increases the number of directors on the Board to seven. Mr. Karsen was appointed to a term ending at the Company's Annual Stockholders' Meeting in 2015, when he is expected to stand for election for another term ending in 2018. Mr. Karsen serves as Chief Operations Officer of Celgene Corporation, and has served in this capacity since July 2010. Mr. Karsen became Executive Vice President and Chief Operations Officer at Celgene Corporation in February 2012. In addition, Mr. Karsen serves as Chief Executive Officer of Celgene Cellular Therapeutics, a position he has held since May, 2013. Mr. Karsen served as President and Chief Executive Officer at Pearl Therapeutics, a privately-held biotechnology company, from February 2009 until July 2010. From 2004 to 2009, Mr. Karsen was Senior Vice President and Head of Worldwide Business Development for Celgene Corporation and was also responsible for emerging businesses as President, Asia/Pacific Region. Prior to his tenure with Celgene Corporation, Mr. Karsen held executive positions at Human Genome Sciences, Bristol-Myers-Squibb, Genentech and Abbott Laboratories. In addition, Mr. Karsen served as a General Partner at Pequot Ventures. Mr. Karsen serves as a member of the Board of Directors of the Biotechnology Industry Organization (BIO); a member of the Board of Directors of BayBio; and a member of the Board of Directors for the Life Sciences Foundation. In addition, Mr. Karsen is a member of the Board of Directors of Agios Pharmaceuticals, a publicly-held biotechnology company, and Alliqua, Inc., a publicly-held provider of wound care solutions and drug delivery technologies. Mr. Karsen has joined the Board in an individual capacity as an outside director, and not as a representative of Celgene Corporation or any other entity or organization. Mr. Karsen has a Masters of Management degree from Northwestern University's Kellogg Graduate School of Management, a Masters in Teaching of Biology from Duke University, and a B.S. in Biological Sciences from the University of Illinois, Urbana. The Board may consider Mr. Karsen for appointment to committees in the future, but currently has no definite plans with respect to committee appointments for Mr. Karsen.

Mr. Karsen will receive cash compensation for his service on the Board consistent with Company policy for all outside directors. In connection with Mr. Karsen's appointment to the Board, the Company has granted Mr. Karsen 20,000 restricted shares of its common stock. The restricted stock was granted under the Company's Fourth Amended and Restated 2002 Stock Incentive Plan, and will vest on the first anniversary of the date of grant. The restricted stock award is the same as paid to other non-executive directors of the Company for their service in 2014. On February 19, 2014, the Company issued a press release entitled "Navidea Biopharmaceuticals Adds New Member to Board of Directors" in connection with the appointment of Mr. Karsen to the Board. A copy the Company's February 19, 2014, press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

**Item 8.01. Other Events.**

On February 18, 2014, the Company issued a press release announcing that the U.S. Food and Drug Administration ("FDA") has accepted the Supplemental New Drug Application ("sNDA") and granted a Priority Review for the expanded use of Lymphoseek® (technetium 99m tilmanocept) Injection indicated for sentinel lymph node detection in patients with head and neck cancer. Under the Prescription Drug User Fee Act, the FDA has set a target review date for the Lymphoseek sNDA of June 16, 2014.

A copy of the complete text of the Company's February 18, 2014, press release is attached as Exhibit 99.2 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, 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.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

| *Exhibit Number* | *Exhibit Description* |
|---|---|
| 99.1 | Navidea Biopharmaceuticals, Inc. press release dated February 19, 2014, entitled "Navidea Biopharmaceuticals Adds New Member to Board of Directors." |
| 99.2 | Navidea Biopharmaceuticals, Inc. press release dated February 18, 2014, entitled "Navidea Announces Priority Review for the sNDA to Expand Lymphoseek® Labeling for Sentinel Lymph Node Detection in Patients with Head and Neck Cancer." |

**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: February 19, 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 Biopharmaceuticals Adds New Member to Board of Directors

DUBLIN, OHIO – February 19, 2013 – Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB), a biopharmaceutical company focused on precision diagnostic radiopharmaceuticals, today announced that Perry A. Karsen has been appointed to the Navidea Board of Directors. Mr. Karsen has more than 30 years of experience in the pharmaceutical and biotechnology industries, including key roles at Celgene Corporation. His appointment increases the number of directors on Navidea's Board to seven.

"We are delighted that Perry has agreed to join the Board," said Gordon Troup, Chairman of the Navidea Board of Directors. "Perry brings a wealth of business development, finance, commercialization and general management experience to Navidea, having held senior positions at some of the leading pharmaceutical and biotech companies. His deep knowledge will be a valuable asset as we continue to pursue our corporate goals."

"I am truly excited to join the impressive board and leadership team that Navidea has assembled to bring new, and important precision diagnostics to patients that will improve diagnostic accuracy, clinical decision-making and patient care," said Mr. Karsen. "I believe Navidea is at an important inflection point in its growth, and I look forward to the opportunity to help Navidea deliver on its potential."

Mr. Karsen is currently Executive Vice President and Chief Operations Officer at Celgene Corporation and Chief Executive Officer of Celgene Cellular Therapeutics. Previously, Mr. Karsen was Senior Vice President and Head of Worldwide Business Development at Celgene, and was also responsible for emerging businesses as President, Asia/Pacific Region. He also served as President and Chief Executive Officer at Pearl Therapeutics and he held executive roles at Human Genome Sciences, Bristol-Myers Squibb, Genentech and Abbott Laboratories. In addition, Mr. Karsen was a General Partner at Pequot Ventures. Mr. Karsen is a member of the Board of Directors of the Biotechnology Industry Organization (BIO); a member of the Board of Directors of BayBio; and a member of the Board of Directors for the Life Sciences Foundation. He is also a member of the Board of Directors of Agios Pharmaceuticals and Alliqua, Inc. Mr. Karsen has a Masters of Management degree from Northwestern University's Kellogg Graduate School of Management, a Masters in Teaching of Biology from Duke University, and a B.S. in Biological Sciences from the University of Illinois, Urbana.

**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 NAV4694, NAV5001, Manocept™ 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 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.

*- more -*

*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

###

*- end -*

Exhibit 99.2

Press Release

**FOR IMMEDIATE RELEASE**

# Navidea Announces Priority Review for the sNDA to Expand Lymphoseek® Labeling for Sentinel Lymph Node Detection in Patients with Head and Neck Cancer

***- Priority review designation of the Supplemental New Drug Application (sNDA) for Lymphoseek shortens the review time -***

**DUBLIN, OHIO – February 18, 2014 --** Navidea Biopharmaceuticals, Inc. (NYSE MKT:NAVB), a biopharmaceutical company focused on precision diagnostic radiopharmaceuticals, announced today that the U.S. Food and Drug Administration (FDA) has accepted the Supplemental New Drug Application (sNDA) and granted a Priority Review for the expanded use of Lymphoseek ® (technetium 99m tilmanocept) Injection indicated for sentinel lymph node (SLN) detection in patients with head and neck cancer. Under the Prescription Drug User Fee Act (PDUFA), the FDA has set a target review date for the Lymphoseek sNDA of June 16, 2014. The FDA grants priority review status to drug applications that may offer a significant improvement in treatment over existing options. Lymphoseek is currently approved for use in lymphatic mapping procedures performed to aid in the diagnostic evaluation of lymph nodes draining a primary tumor in patients with breast cancer and melanoma.

"FDA's acceptance of the Lymphoseek sNDA filing and the granting of a Priority Review for this indication highlights the urgent need of these cancer patients who generally face extensive surgery for a diagnostic evaluation of potential cancer spread and to properly stage their cancer," said Mark Pykett, VMD, PhD, Navidea CEO. "We are encouraged by the Agency's expedited review. If this sNDA is approved, Lymphoseek will be the only FDA-approved diagnostic agent with SLN detection claims, and represents another step forward in Navidea's efforts to develop precision diagnostics that improve the accuracy of diagnosis."

The sNDA submission included data from the NEO3-06 Phase 3 study that showed with statistical significance the ability of Lymphoseek to correctly identify patients with pathology-positive lymph nodes compared with multiple level lymph node dissection and pathology assessment, the current "gold standard". The Phase 3 trial NEO3-06 was a prospective, open-label, multicenter, within-patient study. It was designed to identify sentinel lymph nodes and determine the false negative rate (FNR) associated with Lymphoseek-identified SLNs relative to the pathological status of non-SLNs in head and neck and intraoral squamous cell carcinoma. The primary endpoint for the NEO3-06 trial was based on the number of subjects with pathology-positive lymph nodes (lymph nodes found to harbor cancer) following a multiple level lymph node dissection and required a minimum of 38 subjects whose lymph nodes contained pathology-confirmed disease. FNR is the rate of occurrence of negative test results in subjects known to have the disease for which the individual is being tested. Of the more than 80 subjects enrolled in the NEO3-06 trial, 39 subjects were determined to have pathology-positive lymph nodes. Results demonstrated that Lymphoseek correctly identified 38 of these 39 patients, for an overall FNR of 2.56%, which met the predefined statistical threshold. These findings indicate that Lymphoseek accurately identified SLNs in these trial subjects, and is likely to be predictive of overall node pathology status. Moreover, multiple level nodal dissection of patients in the trial with cancer-positive lymph nodes led to an average removal of 38 lymph nodes per patient, whereas Lymphoseek on average led to the removal of approximately 4 lymph nodes, representing a substantial reduction in potential morbidity for patients with head and neck cancer undergoing single lymph node biopsy.

*- more -*

**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. Lymphoseek was granted Fast Track and Priority Review designation for its supplemental new drug application (sNDA) for sentinel lymph node detection in patients with head and neck cancer.

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 69,500 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 137,000 new cases of head and neck/oral cancer diagnosed in Europe annually.

**U.S. 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).

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 developing multiple precision diagnostic products and platforms including NAV4694, NAV5001, Manocept™ and 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 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

###

*- end -*