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) April 4, 2013

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 8.01. Other Events.

On April 4, 2013, Navidea Biopharmaceuticals, Inc. (the "Company") issued a press release announcing top-line results from the interim analysis of its Phase 3 clinical trial, NEO3-06, of Lymphoseek® (technetium 99m tilmanocept) Injection in patients with head and neck squamous cell carcinoma. Results of the pre-planned interim analysis demonstrated that Lymphoseek met the primary efficacy endpoint of accurately identifying sentinel lymph nodes (SLNs) in subjects with squamous cell carcinoma of the head or in the mouth, as compared to the removal of all lymph nodes during multiple level nodal dissection surgery of the head and neck. Multiple level nodal dissection surgery is considered the "gold standard" to determine the presence and extent of cancer spread in lymph nodes of patients with head and neck squamous cell carcinoma. 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 primary endpoint for the NEO3-06 trial was based on the number of subjects with pathology-positive lymph nodes (that is, 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. Of the over 80 subjects enrolled in the NEO3-06 trial, 39 subjects were determined to have pathology-positive lymph nodes. Results demonstrated that of these 39 patients, Lymphoseek accurately identified 38, for an overall False Negative Rate ("FNR") of 2.56%, which was statistically significant (p=0.0205) and met the statistical threshold for success of the primary endpoint. These findings indicate that Lymphoseek accurately identified SLNs in these trial subjects, and is likely to be predictive of overall node pathology status. FNR is the rate of occurrence of negative test results in subjects known to have the disease for which the individual is being tested. 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 sentinel lymph node biopsy.

A copy of the complete text of the Company's April 4, 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 April 4, 2013, entitled "Navidea Biopharmaceuticals Announces Positive Top-Line Results from Interim Analysis of Lymphoseek® Phase 3 Clinical Trial in 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: April 4, 2013

By: /s/ Brent L. Larson

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

Exhibit 99.1

Navidea Press Release

Navidea Biopharmaceuticals Announces Positive Top-Line Results from Interim Analysis of Lymphoseek® Phase 3 Clinical Trial in Head and Neck Cancer

- Lymphoseek Meets Primary Endpoint in Identification of Sentinel Lymph Nodes Against Pathology Gold Standard -

DUBLIN, OHIO – April 4, 2013 - Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB), a biopharmaceutical company focused on the development and commercialization of precision diagnostic radiopharmaceuticals, today announced top-line results from the interim analysis of its Phase 3 clinical trial, NEO3-06, of Lymphoseek® (technetium 99m tilmanocept) Injection in patients with head and neck squamous cell carcinoma. Results of the pre-planned interim analysis demonstrated that Lymphoseek met the primary efficacy endpoint of accurately identifying sentinel lymph nodes (SLNs) in subjects with squamous cell carcinoma of the head or in the mouth, as compared to the removal of all lymph nodes during multiple level nodal dissection surgery of the head and neck. Multiple level nodal dissection surgery is considered the "gold standard" to determine the presence and extent of cancer spread in lymph nodes of patients with head and neck squamous cell carcinoma. 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.

"These interim results are highly encouraging for this patient population who generally face extensive surgery to properly stage their cancer," said Mark J. Pykett, V.M.D, Ph.D., President and CEO of Navidea. "This study is part of Navidea's strategy to expand Lymphoseek utilization into multiple cancer types and assist physicians in improving the accuracy and extent of cancer diagnosis for their patients. In light of the positive top-line results, and with consideration for the effect of these surgeries on patients, the study's Data Safety Monitoring Committee (DSMC) has recommended that we close the NEO3-06 trial early, a possibility the Company will assess as the full dataset becomes available. We expect to complete the full dataset and secondary analyses of this study, present them at major scientific meetings in the coming months, and evaluate the possibility of filing a Supplemental New Drug Application (sNDA) later this year."

The primary endpoint for the NEO3-06 trial was based on the number of subjects with pathology-positive lymph nodes (that is, 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. Of the over 80 subjects enrolled in the NEO3-06 trial, 39 subjects were determined to have pathology-positive lymph nodes. Results demonstrated that of these 39 patients, Lymphoseek accurately identified 38, for an overall False Negative Rate (FNR) of 2.56%, which was statistically significant ($p=0.0205$) and met the statistical threshold for success of the primary endpoint. These findings indicate that Lymphoseek accurately identified SLNs in these trial subjects, and is likely to be predictive of overall node pathology status. FNR is the rate of occurrence of negative test results in subjects known to have the disease for which the individual is being tested. 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 sentinel lymph node biopsy.

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"In the current standard of care with head and neck tumors, we may systematically remove as many as 60 or more lymph nodes within the neck during a formal dissection procedure, a large number due to the likelihood that patients may have hidden cancer in the lymphatic system," said 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 use of sentinel lymph node biopsy for selected patients with head and neck cancers is in evolution. These combined interim data, along with our initial clinical experience with Lymphoseek, suggest a very high level of accuracy in the identification and mapping of SLNs that may significantly improve the precision and practicality of SLN mapping procedures, and provide precision staging that may help direct post-surgical treatment. We look forward to developing the full potential of this technology for the appropriate patients," added Dr. Lai.

"This clinical study is unique in that it compares the performance of Lymphoseek, a next-generation, receptor-targeted synthetic molecule to the pathological 'gold standard' multiple level dissection procedure in which a large portion of the head and neck lymph node tissue is removed," said Frederick Cope, Ph.D., F.A.C.N., Senior Vice President of Pharmaceutical Research and Drug Development at Navidea. "Achieving this degree of statistical significance versus the pathology of a multiple level dissection is testimony to the accuracy of Lymphoseek in identifying clinically significant lymph nodes through a less invasive diagnostic procedure."

About the Lymphoseek Phase 3 Clinical Trial (NEO3-06) in Head and Neck Cancer

Navidea's Phase 3 clinical trial (NEO3-06) of Lymphoseek is a prospective, open-label, multicenter, within-patient study of Lymphoseek ® (technetium Tc 99m tilmanocept) Injection. It is designed to identify sentinel lymph nodes (SLNs) 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 study is a supplement to previously conducted Phase 3 trials of Lymphoseek in breast cancer and melanoma that were designed to establish Lymphoseek as an effective radiopharmaceutical agent for use in lymphatic mapping procedures to identify the lymph nodes that drain from a primary tumor, which have the highest probability of harboring cancer. Those studies formed the basis of the NDA registration package upon which the U.S. Food and Drug Administration based its approval of Lymphoseek in March, 2013. Navidea is conducting the NEO3-06 clinical study to provide evidence of Lymphoseek performance in a third cancer type and to potentially expand its product label.

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.

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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 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.

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Contact: *Navidea Biopharmaceuticals – Brent Larson, Sr. VP & CFO – (614) 822-2330*

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