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 3, 2012

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 300, Columbus, 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 3, 2012, Navidea Biopharmaceuticals, Inc. (the "Company") issued a press release announcing that it has received notification from the United States Food and Drug Administration (FDA) that the Prescription Drug User Fee Act (PDUFA) date for 99m-Tc-Tilmanocept (Lymphoseek®) has been modified to September 10, 2012, a 90-day extension from the initial PDUFA date of June 10, 2012.

As part of its ongoing support of the Lymphoseek New Drug Application (NDA) review, on March 30, 2012, the Company provided, as requested by the FDA, updated chemistry, manufacturing and control information related to one of several drug analytical assays. As this information was submitted within the 90-day period prior to the PDUFA date, on April 2, 2012, the FDA at its option elected to extend the review period by 90 days to complete a first-cycle evaluation. Neither this decision by the FDA nor the NDA review-to-date has raised questions on Lymphoseek's safety or efficacy. The PDUFA date extension does not pertain to the Company's ongoing head and neck cancer clinical trial or to the recently announced comparative analysis of Lymphoseek to sulfur colloid.

Also on April 3, 2012, the Company issued a press release announcing that data from a meta-analysis comparing 99m-Tc-Tilmanocept (Lymphoseek®) to sulfur colloid were presented at a session of the Sentinel Node Oncology Foundation and International Sentinel Lymph Node Working Group in Orlando, Florida. The presentation by Frederick O. Cope, Ph.D. FACN CNS, the Company's Senior Vice President of Pharmaceutical Research and Clinical Development, described, for the first time, a meta-analysis and pooled-data comparison of results from the Company's prospective Phase 3 clinical trials of Lymphoseek in patients with breast cancer, to historical data on sulfur colloid from documents filed with FDA related to sulfur colloid labeling for breast cancer lymphatic mapping.

Two key parameters were evaluated in the study: (1) the localization rate (LR) of the agents per patient population, and (2) the degree of localization (DL) or number of nodes in which the agent localized per patient. Both parameters were evaluated using meta-analysis and pooled-data approaches. The meta-analyses revealed that in the breast cancer patients studied, Lymphoseek's LR was 99.91% by meta-analysis and 98.65% by pooled data analysis, whereas the sulfur colloid LR derived from peer-reviewed literature was 94.13% ($P<0.0001$/meta-analysis; $p<0.0015$/pooled analysis). Similarly, Lymphoseek's DL in the breast cancer patients studies was 2.1 by meta-analysis and 2.2 by pooled data analysis, compared to the sulfur colloid DL from peer-reviewed literature of 1.6 ($P<0.0001$/meta-analysis; $p<0.0001$/pooled analysis).

These observations with Lymphoseek build on prior data presented by the Company demonstrating the comparison of Lymphoseek over vital blue dye, another agent used in intra-operative lymphatic mapping. Full data on the comparison of Lymphoseek and sulfur colloid will be presented at the American Society for Clinical Oncology (ASCO) Annual Meeting, June 1-5, 2012 in Chicago, IL. Additionally, Dr. Cope also presented the overall Phase 3 clinical trial experience with Lymphoseek in intraoperative lymphatic mapping (ILM) in patients with breast cancer and melanoma.

Copies of the complete text of the Company's April 3, 2012, press releases are attached as Exhibits 99.1 and 99.2 to this Current Report on Form 8-K and are 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 3, 2012, entitled "FDA Extends PDUFA Date for Lymphoseek® by Three Months."
99.2	Navidea Biopharmaceuticals, Inc. press release, dated April 3, 2012, entitled "Navidea Biopharmaceuticals Presents Favorable Comparison of Lymphoseek® to Sulfur Colloid at Sentinel Node Oncology Foundation and Sentinel Lymph Node Working Group."

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 3, 2012

By: /s/ Brent L. Larson

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

Exhibit 99.1

Navidea BIOPHARMACEUTICALS

Press Release

FDA Extends PDUFA Date for Lymphoseek® by Three Months

Lymphoseek Remains on Track for First-Cycle Review

Dublin, OH – April 3, 2012 - Navidea Biopharmaceuticals, Inc. (NYSE Amex: NAVB) today announced that yesterday it received notification from the United States Food and Drug Administration (FDA) that the Prescription Drug User Fee Act (PDUFA) date for 99m-Tc-Tilmanocept (Lymphoseek®), has been modified to September 10, 2012, a 90-day extension from the initial PDUFA date of June 10th. Lymphoseek is an investigational, proprietary radioactive tracing agent for lymphatic mapping and lymphoscintigraphy.

As part of its ongoing support of the Lymphoseek NDA review, on March 30, 2012, the Company provided as requested by the Agency, updated chemistry, manufacturing and control information related to one of several drug analytical assays. As this information was submitted within the 90-day period prior to the PDUFA date, on April 2nd, FDA at its option elected to extend the review period by 90 days to complete a first-cycle evaluation. Neither this FDA decision nor the NDA review-to-date has raised questions on Lymphoseek's safety or efficacy. The PDUFA date extension does not pertain to the Company's ongoing head and neck cancer clinical trial or to the recently announced comparative analysis of Lymphoseek to sulfur colloid.

"We have submitted the information requested by the FDA in support of a first-cycle review of the Lymphoseek NDA," said Mark Pykett, Navidea President and CEO. "Our focus continues to be on supporting the FDA review and preparing for anticipated market introduction of Lymphoseek. All of the clinical data we have generated for Lymphoseek to date support a clear safety and efficacy profile, which we believe holds value to patients and their physicians."

About Lymphoseek

Lymphoseek is a proprietary radioactive tracing agent being developed for use in connection with gamma detection devices in pre-operative lymphoscintigraphy imaging and in a surgical procedure known as Intraoperative Lymphatic Mapping. Lymphoseek works by binding to a specific receptor found on the surface of dendritic cells and macrophages, which reside in high concentration in lymph nodes. This receptor-targeted property of Lymphoseek enables it to attach to and remain within lymph nodes.

Two Phase 3 multi-center clinical trials (www.clinicaltrials.gov, trial registration numbers NCT00671918 and NCT01106040) for Lymphoseek in patients with breast cancer or melanoma have concluded. A third Phase 3 clinical study to evaluate the efficacy of Lymphoseek as a sentinel lymph node tracing agent in patients with head and neck squamous cell carcinoma is currently ongoing (www.clinicaltrials.gov, trial registration number NCT00911326). To date Lymphoseek is the first and only receptor-targeted agent developed specifically for ILM.

About the Lymphoseek NDA Submission

The Lymphoseek NDA submitted by the Company in August 2011 includes results from two complete Phase 3 studies of Lymphoseek, NEO3-05 and NEO3-09, performed in patients with either breast cancer or melanoma. The primary endpoint for both the NEO3-05 and NEO3-09 studies was the concordance (or the rate of agreement) on a lymph node count basis of Lymphoseek with vital blue dye, a long-standing, FDA-approved, on-label agent for lymphatic mapping and appropriate "Truth Standard" comparator for registration purposes. In both of the Phase 3 studies (NEO3-05, NEO3-09), the concordance of Lymphoseek to vital blue dye was highly statistically significant ($p<0.0001$). Lymphoseek met all primary and secondary endpoints across both studies. Secondary endpoints were also assessed, including the false negative rate (or failed detection rate) of Lymphoseek versus vital blue dye. This analysis evaluated the ability of vital blue dye and Lymphoseek to detect lymph nodes that potentially contained cancer cells, as determined by pathology evaluation. In both studies combined, vital blue dye exhibited a failed lymph node detection rate of more than 20%, whereas Lymphoseek showed a failed lymph node detection rate of approximately 1%, or twenty-fold lower than vital blue dye, a difference that was also highly statistically significant ($p<0.002$). Because the key objective of performing ILM is to potentially identify cancer cells when they are present in lymph nodes, reduction of the failed lymph node detection rate is important.

In more than 500 subjects receiving Lymphoseek to date, including those studied as a part of the NEO3-05 and NEO3-09 studies, no drug-related serious adverse events or clinically significant drug-related adverse events have been reported.

About Navidea

Navidea Biopharmaceuticals, Inc. (NYSE Amex: NAVB) is a biopharmaceutical company focused on the development and commercialization of precision diagnostics and radiopharmaceutical agents. Navidea is actively developing three radiopharmaceutical agent platforms – Lymphoseek®, AZD4694 and RIGScan™ – to help identify the presence and status 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, Inc.
Brent Larson, Sr. VP & CFO, 614-822-2330

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Exhibit 99.2

Press Release

Navidea Biopharmaceuticals Presents Favorable Comparison of Lymphoseek® to Sulfur Colloid at Sentinel Node Oncology Foundation and Sentinel Lymph Node Working Group

– Data Point to Promising Comparison to Sulfur Colloid –

DUBLIN OHIO, April 3, 2012 — Navidea Biopharmaceuticals, Inc. (NYSE Amex: NAVB), a specialty pharmaceutical company focused on precision diagnostic radiopharmaceuticals, today announced that data from a meta-analysis comparing 99m-Tc-Tilmanocept (Lymphoseek®) to sulfur colloid were presented at a session of the Sentinel Node Oncology Foundation and International Sentinel Lymph Node Working Group in Orlando, Florida, March 20-21, 2012.

The presentation by Frederick O. Cope, Ph.D. FACN CNS, Navidea's Senior Vice President of Pharmaceutical Research and Clinical Development, described, for the first time, a meta-analysis and pooled-data comparison of results from Navidea's prospective Phase 3 clinical trials of Lymphoseek in patients with breast cancer, to historical data on sulfur colloid from documents filed with FDA related to sulfur colloid labeling for breast cancer lymphatic mapping.

Two key parameters were evaluated in the study: 1] the localization rate (LR) of the agents per patient population, and 2] the degree of localization (DL) or number of nodes in which the agent localized per patient. Both parameters were evaluated using meta-analysis and pooled-data approaches.

The meta-analyses revealed that in the breast cancer patients studied, Lymphoseek's LR was 99.91% by meta-analysis and 98.65% by pooled data analysis, whereas the sulfur colloid LR derived from peer-reviewed literature was 94.13% ($P<0.0001$/meta-analysis; $p<0.0015$/pooled analysis). Similarly, Lymphoseek's DL in the breast cancer patients studies was 2.1 by meta-analysis and 2.2 by pooled data analysis, compared to the sulfur colloid DL from peer-reviewed literature of 1.6 ($P<0.0001$/meta-analysis; $p<0.0001$/pooled analysis).

These observations with Lymphoseek build on prior data presented by the Company demonstrating the comparison of Lymphoseek over vital blue dye, another agent used in intra-operative lymphatic mapping. Full data on the comparison of Lymphoseek and sulfur colloid will be presented at the American Society for Clinical Oncology (ASCO) Annual Meeting, June 1-5, 2012 in Chicago, IL. Additionally, Dr. Cope also presented the overall Phase 3 clinical trial experience with Lymphoseek in intraoperative lymphatic mapping (ILM) in patients with breast cancer and melanoma.

"These analyses, and those contrasting vital blue dyes in our Phase 3 studies, comprise statistical evaluations that provide comparisons with current agents employed in the practice of intraoperative lymphatic mapping (ILM) in breast cancer and melanoma in the U.S.," commented Dr. Cope. "The sum of these data, taken together with the institutional experience of Dr. Stephen Lai of MD Anderson Cancer Center, whose presentation at the recent Society of Surgical Oncology meeting on the use of Lymphoseek in patients with head/neck squamous cell carcinoma, indicates Lymphoseek's potential utility in multiple solid tumors and notable adaptation to multiple anatomical sites. We believe this is due to Lymphoseek's targeted binding to the mannose binding receptors (MBR) within key predictive nodes."

Stanley Leong, M.D., Chairman and President of the Sentinel Node Oncology Foundation, and Head of Melanoma Surgery at Sutter Enterprise, Chief of Cutaneous Surgery at the California Pacific Medical Center and Sutter Pacific Medical Foundation in San Francisco, said, "It was exciting for both foundation and international members of the working group to see the summary data and the specific function of the new agent, tilmanocept. These data initiated significant discussions about new approaches to using targeted agents for ILM and certainly provide a significant contrast to the colloid agents now in use. We are looking forward to the availability of Lymphoseek and its true targeting performance capability."

About Lymphoseek
Lymphoseek is a proprietary radioactive tracing agent being developed for use in connection with gamma detection devices in pre-operative lymphoscintigraphy imaging and in a surgical procedure known as Intraoperative Lymphatic Mapping. Lymphoseek works by binding to a specific receptor found on the surface of dendritic cells and macrophages, which reside in high concentration in lymph nodes. This receptor-targeted property of Lymphoseek enables it to attach to and remain within lymph nodes.

Two Phase 3 multi-center clinical trials for Lymphoseek in subjects with breast cancer or melanoma have been completed (NEO3-05 and NEO3-09; www.clinicaltrials.gov trial registration numbers NCT00671918 and NCT01106040, respectively). A third Phase 3 clinical study to evaluate the efficacy of Lymphoseek as a sentinel lymph node tracing agent in subjects with head and neck squamous cell carcinoma is currently ongoing (NEO3-06; www.clinicaltrials.gov trial registration number NCT00911326).

About ILM and Lymphoscintigraphy
To date, Lymphoseek is the first and only receptor-targeted agent developed specifically for Intraoperative Lymphatic Mapping (ILM). ILM is a surgical oncology procedure in which lymph nodes draining the area around a tumor are identified and biopsied to determine if cancer has spread to the lymph nodes. Lymphoscintigraphy is an imaging procedure routinely performed pre-operatively to provide surgeons with guidance on the relative location of lymph nodes to be biopsied. ILM with a radiopharmaceutical is specifically intended to identify for the surgeon the first lymph node(s) to receive lymphatic flow from the primary tumor site. These "Sentinel Lymph Nodes" are removed and analyzed for the presence of malignant cells. By identifying the Sentinel Lymph Nodes prior to surgery, a small incision and focused dissection can be used to remove them. This technique provides an accurate staging procedure that can help ensure optimal surgical and therapeutic choices, including the avoidance of the morbidity of a complete lymph node dissection for patients in whom the Sentinel Lymph Nodes were found to be free of cancer.

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About Navidea Biopharmaceuticals, Inc.
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