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 1, 2012

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

Delaware	0-26520	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 February 1, 2012, Navidea Biopharmaceuticals, Inc. (the "Company") issued a press release announcing that it intends to file a Marketing Authorization Application ("MAA") in the European Union for Lymphoseek® (Kit for the Preparation of Technetium Tc 99m Tilmanocept for Injection) based on clinical data accumulated from completed pivotal studies and supporting clinical literature. The Company has been advised by the European Medicines Agency's ("EMA") Committee for Medicinal Products for Human Use ("CHMP") that the CHMP has adopted the advice of the Scientific Advice Working Party regarding the Lymphoseek development program and has determined that Lymphoseek is eligible for an MAA submission. Accordingly, the Company has initiated regulatory activities to submit an MAA to the EMA for Lymphoseek by year-end 2012. Preparation of an MAA is typically an extensive undertaking and, in the case of Lymphoseek, will be similar in scope to the Company's New Drug Application submission with the U.S. Food and Drug Administration. The Company will seek clearance to market Lymphoseek for use in Intraoperative Lymphatic Mapping and will also seek to include the use of Lymphoseek in Lymphoscintigraphy imaging procedures. A copy of the complete text of the Company's February 1, 2012, press release is attached 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 February 1, 2012, entitled "Navidea Obtains Positive EMA Guidance for Lymphoseek® (Tilmanocept); Company to Submit Marketing Authorization Application in Europe."

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 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 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, Quarterly Reports on Form 10-Q, and other SEC filings. 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: February 1, 2012

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

Exhibit 99.1

Navidea BIOPHARMACEUTICALS Press Release

FOR IMMEDIATE RELEASE

Navidea Obtains Positive EMA Guidance for Lymphoseek® (Tilmanocept); Company to Submit Marketing Authorization Application in Europe

-- Planned submission to EMA based on pivotal studies, existing data --

February 1, 2012 - DUBLIN, OH - Navidea Biopharmaceuticals, Inc. (NYSE Amex: NAVB), a specialty pharmaceutical company focused on precision diagnostic radiopharmaceuticals, today announced that it intends to file a Marketing Authorization Application (MAA) in the EU for Lymphoseek® (Kit for the Preparation of Technetium Tc 99m Tilmanocept for Injection) based on clinical data accumulated from completed pivotal studies and supporting clinical literature.

Navidea has been advised by the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) that the Committee has adopted the advice of the Scientific Advice Working Party (SAWP) regarding the Lymphoseek development program and has determined that Lymphoseek is eligible for an MAA submission.

Accordingly, Navidea has initiated regulatory activities to submit an MAA to the EMA for Lymphoseek by year-end 2012. Preparation of an MAA is typically an extensive undertaking and in the case of Lymphoseek will be similar in scope to Navidea's New Drug Application (NDA) submission with the U.S. FDA. Navidea will seek clearance to market Lymphoseek for use in Intraoperative Lymphatic Mapping (ILM) and will also seek to include the use of Lymphoseek in Lymphoscintigraphy imaging procedures.

"We are pleased to receive the advice and feedback from the SAWP and CHMP as it provides Navidea with confirmation that our Phase 3 studies were well-designed and, with additional supportive information, provide a strong clinical basis for clearance to market Lymphoseek in the EU," commented Rodger Brown, Navidea Vice President of Regulatory Affairs and Quality Assurance. "This milestone provides us with a clear pathway for the MAA submission."

"The validation of Lymphoseek, its development, the European medical need and opportunity inherent in this progress with the EMA will form a springboard for our ongoing partnership discussions," stated Thomas Tulip, PhD, Navidea EVP and Chief Business Officer. "We have already engaged a number of well-known potential commercial partners in discussions and this development will stimulate even more interest in this important, innovative product. We look forward to completing a mutually beneficial arrangement with one or more of these high quality organizations in the coming months."

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"We are advancing our innovative precision diagnostics portfolio of agents to improve diagnostic accuracy, clinical decision, and patient care for those with serious diseases, including cancer. An MAA submission for Lymphoseek will be an important step forward in addressing a significant medical need for those with solid tumor cancers in Europe," said Mark Pykett, Navidea President and CEO. "We are excited to be formalizing our regulatory approach for Lymphoseek in Europe as we await feedback from the FDA related to the June 10, 2012 PDUFA date. The pending MAA submission reflects our belief in the widespread application and importance of ILM innovation for those in the EU as a first step in the global registration process for Lymphoseek."

About Intraoperative Lymphatic Mapping

Intraoperative lymphatic mapping (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. According to the International Agency for Research on Cancer's Globocan 2008 project approximately 333,000 new cases of breast cancer and 69,000 new cases of melanoma are diagnosed in the EU on an annual basis, with numbers reaching 1.4 million and 200,000, respectively, worldwide.

About Lymphoseek

Lymphoseek is a proprietary radioactive diagnostic tracing agent being developed for use in connection with gamma detection devices 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.

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In more than 500 subjects receiving Lymphoseek to date, including those studied as a part of theNEO3-05 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.

Contact:

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

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