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) October 30, 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 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 October 31, 2012, Navidea Biopharmaceuticals, Inc. (the "Company") issued a press release announcing that on October 30, 2012, the Company filed the resubmission of its new drug application for Lymphoseek® to the U.S. Food and Drug Administration in response to the complete response letter received by the Company in September 2012. Lymphoseek (technetium Tc 99m tilmanocept) Injection is a novel, receptor-targeted, small-molecule, investigational radiopharmaceutical used in lymphatic mapping procedures that are performed to help stage cancer. Lymphoseek is designed to identify the lymph nodes that drain from a primary tumor, which have the highest probability of harboring cancer.

A copy of the complete text of the Company's October 31, 2012, 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 October 31, 2012, entitled "Navidea Biopharmaceuticals Resubmits New Drug Application for Lymphoseek to FDA"

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: November 1, 2012

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

Navidea BIOPHARMACEUTICALS

Press Release

Navidea Biopharmaceuticals Resubmits New Drug Application for Lymphoseek ® to FDA

DUBLIN, OHIO – October 31, 2012 – Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB), a biopharmaceutical company focused on precision diagnostic radiopharmaceuticals, today announced that on October 30, 2012 it filed the resubmission of its Lymphoseek® New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) in response to the Complete Response Letter (CRL) received in September 2012. Lymphoseek (technetium Tc 99m tilmanocept) Injection is a novel, receptor-targeted, small-molecule, investigational radiopharmaceutical used in lymphatic mapping procedures that are performed to help stage cancer. Lymphoseek is designed to identify the lymph nodes that drain from a primary tumor, which have the highest probability of harboring cancer.

"The Company's resubmission of the Lymphoseek NDA is an important step for cancer patients and medical professionals in moving this novel radiopharmaceutical into the practice of medicine," said Mark Pykett, V.M.D., Ph.D., President and CEO of Navidea Biopharmaceuticals. "We have been working diligently with our advisors, contract manufacturers and the FDA to address the third-party cGMP manufacturing deficiencies noted in the FDA's September CRL. While we are unable to predict the timing for FDA review, we believe that the focused scope of the CRL and the corresponding information provided in the Company's responses will facilitate a timely evaluation of the resubmission. Upon Lymphoseek's approval, we stand prepared to move forward quickly with our U.S. commercialization partner, Cardinal Health."

Dr. Pykett added, "We continue to believe the FDA review process will involve re-evaluation of only a small portion of the NDA concerning third-party manufacturer cGMP compliance and that the focused information we have provided will support a potentially expeditious review. Our clear priority continues to be Lymphoseek approval and launch in the U.S. We are also committed to advancing the development and potential market introduction of this important radiopharmaceutical innovation globally, including filing our Marketing Authorization Application (MAA) for approval in the European Union and advancing our discussions with potential partners outside the U.S., all in an effort to make Lymphoseek available to cancer surgery patients and their physicians worldwide. We also look forward to continuing to advance the other assets in our promising, late-stage pipeline of precision diagnostic agents addressing cancer, Alzheimer's disease and Parkinson's disease."

About Lymphoseek®

Lymphoseek® (technetium Tc 99m tilmanocept) Injection is a novel, receptor-targeted, small-molecule, investigational radiopharmaceutical used in lymphatic mapping procedures that are performed to help stage 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.

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Lymphatic mapping is a procedure in which lymph nodes that may contain tumor metastases are identified and biopsied to determine if cancer has spread beyond the primary tumor. Accurate staging of cancer is critical, as it guides therapy decisions and determines patient prognosis and risk of recurrence. According to the American Cancer Society, approximately 229,000 new cases of breast cancer and 76,000 new cases of melanoma are expected to be diagnosed in the United States in 2012.

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 (CFT) 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.

Contact:

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

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