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) September 10, 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 September 10, 2012, Navidea Biopharmaceuticals, Inc. issued a press release announcing that it received a Complete Response Letter ("CRL") from the U.S. Food and Drug Administration ("FDA") regarding its New Drug Application ("NDA") for Lymphoseek® (technetium Tc 99m tilmanocept) Injection. In the CRL, the FDA noted the decision was focused on issues with third-party Lymphoseek contract manufacturing, and was not related to any efficacy or safety data filed within the Lymphoseek NDA.

A copy of the complete text of the Company's September 10, 2012, press releases is attached as Exhibits 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 September 10, 2012, entitled "Navidea Biopharmaceuticals Receives Complete Response Letter From FDA for Lymphoseek® NDA due to Manufacturing Deficiencies."

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: September 11, 2012

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

Exhibit 99.1

Press Release

NAVIDEA BIOPHARMACEUTICALS RECEIVES COMPLETE RESPONSE LETTER FROM FDA FOR LYMPHOSEEK® NDA DUE TO MANUFACTURING DEFICIENCIES

CRL Unrelated to Lymphoseek® Efficacy and Safety Data

Conference Call Scheduled for 4:45 p.m. ET September 10, 2012

DUBLIN, OHIO (September 10, 2012) -- Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB), a biopharmaceutical company focused on precision diagnostic radiopharmaceuticals, today announced that it received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) regarding its New Drug Application (NDA) for Lymphoseek ® (technetium Tc 99m tilmanocept) Injection. In the CRL, the FDA noted the decision was focused on issues with third-party Lymphoseek contract manufacturing, and was not related to any efficacy or safety data filed within the Lymphoseek NDA.

Lymphoseek is a novel agent that has been studied in lymphatic mapping procedures performed to help stage breast cancer and melanoma. Lymphoseek is a receptor-targeted radiopharmaceutical designed to identify the lymph nodes that drain from a primary tumor, which have the highest probability of harboring cancer.

“Receiving a Complete Response Letter is clearly disappointing. However, we remain steadfast in our belief that Lymphoseek holds significant promise in improving the lives of patients who undergo lymphatic mapping procedures to stage solid tumor cancers, such as breast cancer and melanoma,” said Mark Pykett, V.M.D, Ph.D., President and CEO of Navidea Biopharmaceuticals. “We are already working closely with the FDA and our third-party contract manufacturers to address all requirements to support the shortest possible NDA resubmission and review. We remain confident that our clinical data clearly demonstrate the value of Lymphoseek in accurately identifying lymph nodes that most likely harbor cancer while producing no clinically significant adverse effects,” Pykett added.

Navidea Biopharmaceuticals will provide additional information during a conference call scheduled for 4:45 p.m. EST, September 10, 2012. The conference call can be accessed as follows:

CONFERENCE CALL INFORMATION			
TO PARTICIPATE LIVE:		**TO LISTEN TO A REPLAY:**	
Date:	Sept 10, 2012	Available until:	Sept 25, 2012
Time:	4:45 PM ET	Toll-free (U.S.) Dial in # :	(877) 660-6853
		International Dial in # :	(201) 612-7415
Toll-free (U.S.) Dial in # :	(877) 407-9205		
International Dial in # :	(201) 689-8054	Replay passcode:	
		Account #	286
		Conference ID #:	400036

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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 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, in patients with breast cancer or melanoma.

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 Lymphatic Mapping

Lymphatic mapping is a procedure designed to guide lymph node dissection and biopsy procedures. It consists of Intraoperative Lymphatic Mapping (ILM) often accompanied by lymphoscintigraphy. Lymphoscintigraphy is an imaging procedure routinely performed pre-operatively to provide guidance on the location of lymph nodes to be biopsied. ILM is a surgical 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. These nodes, commonly referred to as "Sentinel Lymph Nodes," are removed and analyzed for the presence of malignant cells. Lymphatic Mapping 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.

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, 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.

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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.

Investor Contact:
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