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 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 October 10, 2012, Navidea Biopharmaceuticals, Inc. (the "Company") issued a press release announcing that it had posted an update on the status of the Lymphoseek® (technetium Tc 99m tilmanocept) Injection ("Lymphoseek") new drug application ("NDA") review on the Company's website. The update stated that, as part of its continuing effort to secure regulatory NDA approval for Lymphoseek, a Type A meeting with the United States Food and Drug Administration ("FDA") had been scheduled to advance the Company's planned response to the FDA regarding deficiencies in current Good Manufacturing Practice ("cGMP") identified during inspections at third-party manufacturing facilities.

The Company has now successfully completed the Type A meeting with the FDA and has received clarifying guidance from the Agency in regard to the cGMP issues noted in the FDA's Complete Response Letter ("CRL") received on September 10, 2012, and the requirements for the Company's response to the CRL for the Lymphoseek NDA. The meeting confirmed that the scope of the Company's resubmission will be focused on the previously noted cGMP manufacturing deficiencies observed at third-party manufacturing facilities. The meeting further affirmed the requirements that the Company must address in its resubmission.

A copy of the complete text of the Company's October 10, 2012, press release, and the referenced update on the status of the Lymphoseek NDA, are attached as Exhibit 99.1 and 99.2, respectively, 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 October 10, 2012, entitled "Navidea Biopharmaceuticals Posts Lymphoseek® NDA Update to Company Website."
99.2	Navidea Biopharmaceuticals, Inc. update, posted October 10, 2012, entitled "Navidea Provides Lymphoseek® NDA Update Statement."

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: October 10, 2012

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

Exhibit 99.1

Press Release

Navidea Biopharmaceuticals Posts Lymphoseek® NDA Update to Company Website

DUBLIN, OHIO – October 10, 2012 – Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB), a biopharmaceutical company focused on the development and commercialization of precision diagnostics and radiopharmaceutical agents, today posted on its website an update to the status of the Lymphoseek NDA review. The web access to the statement can be found on the Navidea Investor page at: http://phx.corporate-ir.net/phoenix.zhtml?c=68527&p=irol-nda

Contact:

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

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Exhibit 99.2

Navidea Provides Lymphoseek® NDA Update Statement

October 10, 2012

On September 24, 2012, Navidea issued a statement that, as part of its continuing effort to secure regulatory NDA approval for Lymphoseek® (technetium Tc 99m tilmanocept) Injection, a Type A meeting with the FDA had been scheduled to advance the Company's planned response to the Agency regarding deficiencies in current Good Manufacturing Practice (cGMP) identified during inspections at third-party manufacturing facilities.

The Company has now successfully completed the Type A meeting with the FDA and has received clarifying guidance from the Agency in regard to the cGMP issues noted in the FDA's Complete Response Letter (CRL) received on September 10, 2012 and the requirements for the Company's response to the CRL for the Lymphoseek NDA.

The meeting confirmed that the scope of the Navidea resubmission will be focused on the previously noted cGMP manufacturing deficiencies observed at third-party manufacturing facilities. The meeting further affirmed the requirements that the Company must address in its resubmission.

The Company continues to believe this process will not entail a re-review of the full NDA. The Company also believes that a majority of the requirements needed from the third-party manufacturing facilities to address the noted deficiencies have already been completed.

Navidea anticipates providing further information regarding the timing for resubmission and related matters by early November. Gaining approval for Lymphoseek continues to be the priority of the Company as we continue to develop our pipeline and advance Navidea's position as a leading precision diagnostics company.

Safe Harbor Statement

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 on this web page, 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.