NAVIDEA BIOPHARMACEUTICALS, INC.
Form 8-K
March 13, 2013

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) March 13, 2013

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 March 13, 2013, Navidea Biopharmaceuticals, Inc. (the "Company") issued a press release announcing U.S. Food and Drug Administration (FDA) approval of Lymphoseek® (technetium Tc 99m tilmanocept) Injection, a novel product indicated for use in lymphatic mapping procedures to assist in the localization of lymph nodes draining a primary tumor in patients with breast cancer or melanoma. Lymphoseek is a receptor targeted radiopharmaceutical designed to identify these lymph nodes which have the highest probability of harboring cancer and thereby assist physicians in the staging of such patients. The approval of Lymphoseek is based on data from more than 540 subjects receiving Lymphoseek. In pivotal Phase 3 studies that were conducted in 332 patients with either breast cancer or melanoma, Lymphoseek, on average, was present in 97% (range 94-100%) of resected, histology-confirmed lymph nodes. To date, no clinically significant drug-related adverse reactions have been reported. Lymphoseek has no contraindications and the most common adverse reactions were injection site irritation and/or pain (<1%).

Lymphoseek will be sold and distributed in the U.S. on an exclusive basis by Cardinal Health, Inc. As part of the distribution agreement, Cardinal Health's Nuclear Pharmacy Services business will be responsible for commercializing and dispensing Lymphoseek to health care professionals who are involved in lymphatic mapping. The Company is also working to identify and partner with distributors in other markets outside of the U.S. The Company will play an ongoing role in commercial activities through focused deployment of medical science liaison and medical education activities. This is consistent with the Company's overall strategy to remain involved in market-based activities with its products while leveraging the extensive capabilities and infrastructure of partners around the world.

A copy of the complete text of the Company's March 13, 2013 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 March 13, 2013, entitled “FDA Approves Navidea’s Lymphoseek® (technetium Tc 99m tilmanocept) Injection for Use in Lymphatic Mapping.”

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: March 13, 2013 By: /s/ Brent L. Larson
Brent L. Larson, Senior Vice President and

Chief Financial Officer