NAVIDEA BIOPHARMACEUTICALS, INC.
Form 8-K
February 01, 2012

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.

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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