

NAVIDEA BIOPHARMACEUTICALS, INC.

Form 8-K

November 13, 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) November 13, 2012

NAVIDEA BIOPHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware 001-35076 31-1080091
(State or other jurisdiction (Commission (IRS Employer
of incorporation) File Number) 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.)

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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 2.02. Results of Operations and Financial Condition.

On November 13, 2012, Navidea Biopharmaceuticals, Inc. (the “Company”) issued a press release announcing that the U.S. Food and Drug Administration (“FDA”) has accepted the filing of the Company's October 30, 2012, resubmission of its New Drug Application (NDA) for Lymphoseek (Technetium Tc 99m Tilmanocept) Injection. In its acknowledgment, FDA noted that it considers the filing a complete, class 2 response to its September 10, 2012 action letter and has set a Prescription Drug User Fee Act (PDUFA) goal date of April 30, 2013. Lymphoseek 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 Company’s November 13, 2012, press release is furnished 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 November 13, 2012, entitled “Navidea Biopharmaceuticals Announces PDUFA Goal Date for Lymphoseek® New Drug Application Resubmission.”

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 filings with the United States Securities and Exchange Commission. The Company undertakes no obligation to publicly update or revise any forward-looking statements.

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 13, 2012 By: /s/ Brent L. Larson

Brent L. Larson,
Senior Vice
President and

Chief Financial
Officer