

NAVIDEA BIOPHARMACEUTICALS, INC.

Form 8-K

May 01, 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) May 1, 2013

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 8.01. Other Events.

On May 1, 2013, Navidea Biopharmaceuticals, Inc. (the “Company”) issued a press release announcing the U.S. launch of Lymphoseek® (technetium Tc 99m tilmanocept) Injection for use in lymphatic mapping procedures that are performed to help in the diagnostic evaluation of potential cancer spread for patients with breast cancer and melanoma. Lymphoseek was approved by the U.S. Food and Drug Administration in March 2013. As part of the Company’s U.S. distribution partnership, Cardinal Health is responsible for the sale and distribution of Lymphoseek to health care professionals through its existing network of nuclear pharmacies. The Company is working closely with Cardinal Health in all commercial activities and medical education programs for Lymphoseek.

Lymphoseek has been priced at \$300 per patient procedure. The Company has been working to ensure fair and equitable reimbursement for lymphatic mapping procedures using Lymphoseek. In the case of Medicare, the Company believes these procedures are currently reimbursable under established codes, and expects to apply for and receive a unique pass-through code for Lymphoseek within a few months. The Company and Cardinal Health will provide information and support to providers and payers to ensure that they can secure formulary status and appropriate payment.

A copy of the complete text of the Company’s May 1, 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 May 1, 2013, entitled “Navidea Biopharmaceuticals Announces the U.S. Launch of Lymphoseek.”

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: May 1, 2013 By: /s/ Brent L. Larson

Brent L. Larson,
Senior Vice
President and

Chief Financial
Officer