

NAVIDEA BIOPHARMACEUTICALS, INC.

Form 8-K

September 12, 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) September 10, 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.)

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):

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- “ 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 September 10, 2012, Navidea Biopharmaceuticals, Inc. issued a press release announcing that it received a Complete Response Letter (“CRL”) from the U.S. Food and Drug Administration (“FDA”) regarding its New Drug Application (“NDA”) for Lymphoseek® (technetium Tc 99m tilmanocept) Injection. In the CRL, the FDA noted the decision was focused on issues with third-party Lymphoseek contract manufacturing, and was not related to any efficacy or safety data filed within the Lymphoseek NDA.

A copy of the complete text of the Company’s September 10, 2012, press releases is attached as Exhibits 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 September 10, 2012, entitled “Navidea Biopharmaceuticals Receives Complete Response Letter From FDA for Lymphoseek® NDA due to Manufacturing Deficiencies.”

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: September 11, 2012 By: /s/ Brent L. Larson
Brent L. Larson, Senior Vice President and
Chief Financial Officer