NAVIDEA BIOPHARMACEUTICALS, INC.
Form 8-K
June 16, 2014

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) June 13, 2014

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.)

5600 Blazer Parkway, Suite 200, 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 7.01 Regulation FD Disclosure.

On June 16, 2014, in the conference call announced in the press release referenced in Item 8.01 below, Dr. Michael Goldberg, Interim CEO of Navidea Biopharmaceuticals, Inc. (the "Company") stated that, as a result of the previously announced reorganization plan to reduce the Company's cash burn, the Company's previous 2014 research and development expense guidance of between $25 to $30 million is being reduced to less than $20 million for the calendar year.

Item 8.01. Other Events.

On June 13, 2014, the Company issued a press release announcing U.S. Food and Drug Administration (FDA) approval of its Supplemental New Drug Application (sNDA) for the expanded use of Lymphoseek® (technetium Tc 99m tilmanocept) Injection indicated for guiding sentinel lymph node (SLN) biopsy in head and neck cancer patients with squamous cell carcinoma of the oral cavity**.** Lymphoseek becomes the first and only FDA-approved radiopharmaceutical application for SLN detection and was first approved in March 2013 for lymphatic mapping in breast cancer and melanoma patients.

The expanded approval is supported by data from Navidea's NEO3-06 prospective Phase 3 study that showed with statistical significance the ability of Lymphoseek to correctly identify patients with pathology-positive lymph nodes compared with multiple level lymph node dissection and pathology assessment, which is the current "gold standard." The findings indicate that Lymphoseek accurately identified SLNs in the trial subjects for assessment, and is likely to be predictive of overall node pathology status. Moreover, multiple level nodal dissections of patients in the trial with cancer-positive lymph nodes led to an average removal of 38 lymph nodes per patient, whereas Lymphoseek on average would have led to the removal of approximately 4 lymph nodes, representing a substantial reduction in potential morbidity for patients with head and neck cancer undergoing SLN biopsy.

A copy of the complete text of the Company's June 13, 2014 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 June 13, 2014, entitled "U.S. FDA Approves Navidea Biopharmaceuticals' Lymphoseek® (technetium Tc 99m tilmanocept) Injection for Expanded Use in Head and Neck Cancer Sentinel Lymph Node Biopsy." *

* Filed herewith

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: June 16, 2014 By: /s/ Brent L. Larson
Brent L. Larson, Executive Vice President and Chief Financial Officer