NAVIDEA BIOPHARMACEUTICALS, INC.
Form 8-K
April 04, 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) April 4, 2013

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.)

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):

¨ 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 April 4, 2013, Navidea Biopharmaceuticals, Inc. (the "Company") issued a press release announcing top-line results from the interim analysis of its Phase 3 clinical trial, NEO3-06, of Lymphoseek® (technetium 99m tilmanocept) Injection in patients with head and neck squamous cell carcinoma. Results of the pre-planned interim analysis demonstrated that Lymphoseek met the primary efficacy endpoint of accurately identifying sentinel lymph nodes (SLNs) in subjects with squamous cell carcinoma of the head or in the mouth, as compared to the removal of all lymph nodes during multiple level nodal dissection surgery of the head and neck. Multiple level nodal dissection surgery is considered the "gold standard" to determine the presence and extent of cancer spread in lymph nodes of patients with head and neck squamous cell carcinoma. Lymphoseek was approved by the U.S. Food and Drug Administration in March, 2013 for use in lymphatic mapping to assist in the localization of lymph nodes draining a primary tumor in patients with breast cancer or melanoma.

The primary endpoint for the NEO3-06 trial was based on the number of subjects with pathology-positive lymph nodes (that is, lymph nodes found to harbor cancer) following a multiple level lymph node dissection and required a minimum of 38 subjects whose lymph nodes contained pathology-confirmed disease. Of the over 80 subjects enrolled in the NEO3-06 trial, 39 subjects were determined to have pathology-positive lymph nodes. Results demonstrated that of these 39 patients, Lymphoseek accurately identified 38, for an overall False Negative Rate ("FNR") of 2.56%, which was statistically significant (p=0.0205) and met the statistical threshold for success of the primary endpoint. These findings indicate that Lymphoseek accurately identified SLNs in these trial subjects, and is likely to be predictive of overall node pathology status. FNR is the rate of occurrence of negative test results in subjects known to have the disease for which the individual is being tested. Moreover, multiple level nodal dissection 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 led to the removal of approximately 4 lymph nodes, representing a substantial reduction in potential morbidity for patients with head and neck cancer undergoing sentinel lymph node biopsy.

A copy of the complete text of the Company's April 4, 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 April 4, 2013, entitled "Navidea Biopharmaceuticals Announces Positive Top-Line Results from Interim Analysis of Lymphoseek® Phase 3 Clinical Trial in Head and Neck Cancer."

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: April 4, 2013 By:/s/ Brent L. Larson
Brent L. Larson, Senior Vice President and
Chief Financial Officer