NAVIDEA BIOPHARMACEUTICALS, INC.
Form 8-K
April 03, 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) April 3, 2012

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 300, Columbus, 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 3, 2012, Navidea Biopharmaceuticals, Inc. (the "Company") issued a press release announcing that it has received notification from the United States Food and Drug Administration (FDA) that the Prescription Drug User Fee Act (PDUFA) date for 99m-Tc-Tilmanocept (Lymphoseek®) has been modified to September 10, 2012, a 90-day extension from the initial PDUFA date of June 10, 2012.

As part of its ongoing support of the Lymphoseek New Drug Application (NDA) review, on March 30, 2012, the Company provided, as requested by the FDA, updated chemistry, manufacturing and control information related to one of several drug analytical assays. As this information was submitted within the 90-day period prior to the PDUFA date, on April 2, 2012, the FDA at its option elected to extend the review period by 90 days to complete a first-cycle evaluation. Neither this decision by the FDA nor the NDA review-to-date has raised questions on Lymphoseek's safety or efficacy. The PDUFA date extension does not pertain to the Company's ongoing head and neck cancer clinical trial or to the recently announced comparative analysis of Lymphoseek to sulfur colloid.

Also on April 3, 2012, the Company issued a press release announcing that data from a meta-analysis comparing 99m-Tc-Tilmanocept (Lymphoseek®) to sulfur colloid were presented at a session of the Sentinel Node Oncology Foundation and International Sentinel Lymph Node Working Group in Orlando, Florida. The presentation by Frederick O. Cope, Ph.D. FACN CNS, the Company's Senior Vice President of Pharmaceutical Research and Clinical Development, described, for the first time, a meta-analysis and pooled-data comparison of results from the Company's prospective Phase 3 clinical trials of Lymphoseek in patients with breast cancer, to historical data on sulfur colloid from documents filed with FDA related to sulfur colloid labeling for breast cancer lymphatic mapping.

Two key parameters were evaluated in the study: (1) the localization rate (LR) of the agents per patient population, and (2) the degree of localization (DL) or number of nodes in which the agent localized per patient. Both parameters were evaluated using meta-analysis and pooled-data approaches. The meta-analyses revealed that in the breast cancer patients studied, Lymphoseek's LR was 99.91% by meta-analysis and 98.65% by pooled data analysis, whereas the sulfur colloid LR derived from peer-reviewed literature was 94.13% ($P<0.0001$/meta-analysis; $p<0.0015$/pooled analysis). Similarly, Lymphoseek's DL in the breast cancer patients studies was 2.1 by meta-analysis and 2.2 by pooled data analysis, compared to the sulfur colloid DL from peer-reviewed literature of 1.6 ($P<0.0001$/meta-analysis; $p<0.0001$/pooled analysis).

These observations with Lymphoseek build on prior data presented by the Company demonstrating the comparison of Lymphoseek over vital blue dye, another agent used in intra-operative lymphatic mapping. Full data on the comparison of Lymphoseek and sulfur colloid will be presented at the American Society for Clinical Oncology (ASCO) Annual Meeting, June 1-5, 2012 in Chicago, IL. Additionally, Dr. Cope also presented the overall Phase 3 clinical trial experience with Lymphoseek in intraoperative lymphatic mapping (ILM) in patients with breast cancer and melanoma.

Copies of the complete text of the Company's April 3, 2012, press releases are attached as Exhibits 99.1 and 99.2 to this Current Report on Form 8-K and are 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 3, 2012, entitled “FDA Extends PDUFA Date for Lymphoseek® by Three Months.”
99.2	Navidea Biopharmaceuticals, Inc. press release, dated April 3, 2012, entitled “Navidea Biopharmaceuticals Presents Favorable Comparison of Lymphoseek® to Sulfur Colloid at Sentinel Node Oncology Foundation and Sentinel Lymph Node Working Group.”

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 3, 2012 By: /s/ Brent L. Larson
Brent L. Larson, Senior Vice President and
Chief Financial Officer