

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

FOR IMMEDIATE RELEASE

U.S. FDA Approves Navidea Biopharmaceuticals' Lymphoseek® (technetium Tc 99m tilmanocept) Injection for Expanded Use in Head and Neck Cancer Sentinel Lymph Node Biopsy

– Lymphoseek is first and only FDA-approved sentinel lymph node biopsy agent for use in head and neck cancer patients with oral cavity carcinoma –

– Lymphoseek now available for multiple patient populations using existing reimbursement codes –

– Company to Host Conference Call on Monday, June 16, 2014, 8:30 a.m. EDT –

DUBLIN OHIO, June 13, 2014 -- Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB), a biopharmaceutical company focused on precision diagnostic radiopharmaceuticals, today announced that the U.S. Food and Drug Administration (FDA) has approved the 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 sentinel lymph node detection and was first approved in March 2013 for lymphatic mapping in breast cancer and melanoma patients.

"In the current standard of care for certain head and neck tumors, such as oral cavity cancers, as many as 30 or more lymph nodes may be removed during a surgical procedure. While sentinel lymph node mapping may be an effective alternative to elective neck dissection, adoption of this approach has been slow in the U.S. because of the lack of an FDA-approved agent with favorable characteristics for use in the head and neck region," said Stephen Y. Lai, M.D., Ph.D., FACS, Associate Professor, Department of Head and Neck Surgery, The University of Texas MD Anderson Cancer Center. "This underscores the urgent need Lymphoseek may be able to address in improving the precision of SLN mapping and decreasing nodal excision to an average of only four lymph nodes. As a result, Lymphoseek offers the potential to more effectively stage certain cancers, direct post-surgical treatment and decrease patient morbidity."

"Our community eagerly welcomes a diagnostic aid such as Lymphoseek that may allow for a less invasive surgical procedure for patients with oral, head, and neck cancers," said Nancy Leupold, Founder & President of Support for People with Oral, Head, and Neck Cancer. "According to the National Cancer Institute, oral, head, and neck cancers account for approximately three percent of all malignancies in the United States, however, post-procedural side effects are more severe than with many other types of cancer. Significant changes in a patient's facial and neck appearance may be present. In addition, a patient may have difficulty with chewing, swallowing, smelling, tasting, speaking and hearing in addition to dental problems."

"With this approval, Lymphoseek is now the only FDA-approved diagnostic agent with a label for guiding sentinel lymph node biopsy procedures and will be immediately available with the existing reimbursement codes for this expanded population of cancer patients," said Michael Goldberg M.D., Navidea Interim Chief Executive Officer. "Navidea intends to continue its investment in Lymphoseek to further expand its use in other types of cancer, where current alternatives are neither efficient nor effective. We believe Lymphoseek can play a critical role in the staging and treatment of cancer, with potential for additional procedural cost savings."

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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 sentinel lymph node biopsy.

The FDA granted the Lymphoseek application Fast Track Designation in December 2013 and Priority Review in February 2014. Fast Track Designation and FDA Priority Review are awarded to drug applications to expedite review of drug candidates intended to treat serious or life-threatening conditions, that demonstrate the potential to address unmet medical needs and may offer a significant improvement in treatment over existing options. Navidea has an additional sNDA under review at the FDA to further expand the Lymphoseek label. This second sNDA focuses on more flexible and extended utilization practices, and has been assigned a PDUFA date set for October 16, 2014.

Conference Call Details

Navidea will host a conference call with the investment community to discuss the sNDA scheduled for Monday, June 16, 2014 at 08:30 a.m. EDT. Investors and the public are invited to access the live webcast through the link below. Participants who would like to ask questions during the question and answer session following the presentation must participate by telephone also. Participants are encouraged to log-in and/or dial-in fifteen minutes before the conference call begins. The webcast replay is expected to be available on our investor website, <http://ir.navidea.com>, approximately two to four hours after the live event.

Event:	Navidea Biopharmaceuticals sNDA Approval Call
Date/Time:	Monday, June 16, 2014 at 08:30 a.m. EDT
Webcast Link:	http://public.viavid.com/index.php?id=109550
Dial-in Number – US:	1-877-407-0789
Dial in Number – Int'l:	1-201-689-8562
Replay	A webcast replay will be available on the Investor Relations section of our website at http://ir.navidea.com .

About Lymphoseek®

Lymphoseek® (technetium Tc 99m tilmanocept) Injection is the first and only FDA-approved receptor-targeted lymphatic mapping agent. It is a novel, receptor-targeted, small-molecule radiopharmaceutical used in the evaluation of lymphatic basins that may have cancer involvement in patients with breast cancer, melanoma and head and neck cancer patients with oral cavity carcinoma. Lymphoseek is designed for the precise identification of lymph nodes that drain from a primary tumor, which have the highest probability of harboring cancer. Lymphoseek is approved by the U.S. Food and Drug Administration (FDA) for use in lymphatic mapping to assist in the localization of lymph nodes draining a primary tumor in patients with breast cancer or melanoma and for use in guiding sentinel lymph node biopsy in head and neck cancer patients with squamous cell carcinoma of the oral cavity. The Company anticipates continuing development of Lymphoseek into other solid tumor areas.

Accurate diagnostic evaluation of cancer is critical, as it guides therapy decisions and determines patient prognosis and risk of recurrence. According to publicly available information, approximately 235,000 new cases of breast cancer, 76,000 new cases of melanoma and 45,000 new cases of head and neck/oral cancer are expected to be diagnosed in the United States in 2014, and approximately 367,000 new cases of breast cancer, 83,000 new cases of melanoma and 55,000 new cases of head and neck/oral cancer diagnosed in Europe annually.

Lymphoseek Indication and Important Safety Information

Lymphoseek (technetium Tc 99m tilmanocept) Injection is indicated, using a hand-held gamma counter, for:

- Lymphatic mapping to assist in the localization of lymph nodes draining a primary tumor site in patients with breast cancer or melanoma.
- Guiding sentinel lymph node biopsy, in patients with clinically node negative squamous cell carcinoma (SCC) of the oral cavity.

Important Safety Information

In clinical trials with Lymphoseek, no serious hypersensitivity reactions were reported, however Lymphoseek may pose a risk of such reactions due to its chemical similarity to dextran. Serious hypersensitivity reactions have been associated with dextran and modified forms of dextran (such as iron dextran drugs).

Prior to the administration of Lymphoseek, patients should be asked about previous hypersensitivity reactions to drugs, in particular dextran and modified forms of dextran. Resuscitation equipment and trained personnel should be available at the time of Lymphoseek administration, and patients observed for signs or symptoms of hypersensitivity following injection.

Any radiation-emitting product may increase the risk for cancer. Adhere to dose recommendations and ensure safe handling to minimize the risk for excessive radiation exposure to patients or health care workers. In clinical trials, no patients experienced serious adverse reactions and the most common adverse reactions were injection site irritation and/or pain (<1%).

FULL LYMPHOSEEK PRESCRIBING INFORMATION CAN BE FOUND AT:
WWW.LYMPHOSEEK.COM

About Navidea Biopharmaceuticals Inc.

Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB) is a biopharmaceutical company focused on the development and commercialization of precision diagnostics and radiopharmaceutical agents. Navidea is developing multiple precision diagnostic products and platforms, including NAV4694, NAV5001, Manocept™ and NAV1800 (RIGScan™), to help identify the sites and pathways of undetected disease and enable better diagnostic accuracy, clinical decision-making and, ultimately, patient care. Lymphoseek® (technetium Tc 99m tilmanocept) Injection, Navidea's first commercial product from the Manocept platform, was approved by the FDA in March 2013. Navidea's strategy is to deliver superior growth and shareholder return by bringing to market novel radiopharmaceutical agents and advancing the Company's pipeline through selective acquisitions, global partnering and commercialization efforts. For more information, please visit www.navidea.com.

The Private Securities Litigation Reform Act of 1995 (the Act) provides a safe harbor for forward-looking statements made by or on behalf of the Company. Statements in this news release, 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 within the meaning of the Act. 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.

Source: Navidea Biopharmaceuticals, Inc.

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or
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Associate Director, Corporate Communications

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