

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 4, 2014

NAVIDEA BIOPHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

<u>Delaware</u> (State or other jurisdiction of incorporation)	<u>001-35076</u> (Commission File Number)	<u>31-1080091</u> (IRS Employer Identification No.)
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<u>5600 Blazer Parkway, Suite 200, Dublin, Ohio</u> (Address of principal executive offices)	<u>43017</u> (Zip Code)
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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 September 4, 2014, Navidea Biopharmaceuticals, Inc. (the “Company”) issued a press release announcing an exclusive agreement with a wholly-owned subsidiary of Hainan Sinotau Pharmaceutical Co., Ltd. A copy of the Company’s September 4, 2014, press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit

Number

Exhibit Description

99.1	Navidea Biopharmaceuticals, Inc. press release dated September 4, 2014, entitled “Navidea Enters Lymphoseek Development and Commercialization Agreement for China.”
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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, 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, 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, and other risks detailed in the Company’s most recent Annual Report on Form 10-K and other filings with the United States Securities and Exchange Commission. The Company undertakes no obligation to publicly update or revise any forward-looking statements.

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 10, 2014

By: /s/ Brent L. Larson

Brent L. Larson, Executive Vice President and
Chief Financial Officer



Press Release

FOR IMMEDIATE RELEASE

Navidea Enters Lymphoseek[®] Development and Commercialization Agreement for China

DUBLIN OHIO September 4, 2014 -- Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB) has entered an exclusive agreement with a wholly-owned subsidiary of Hainan Sinotau Pharmaceutical Co., Ltd., a pharmaceutical organization with a broad China focus in oncology and other therapeutic areas, who will develop and commercialize Lymphoseek[®] (technetium Tc 99m tilmanocept) Injection in China. In exchange, Navidea will earn revenue based on unit sales to Sinotau, a royalty based on Sinotau's sales of Lymphoseek and up to \$2.5 million in milestones from Sinotau, including a \$300,000 upfront payment. Lymphoseek is a novel, receptor-targeted, small-molecule radiopharmaceutical approved in the U.S. for use in lymphatic mapping to assist in the detection of lymph nodes in patients with breast cancer or melanoma and for use in guiding sentinel lymph node biopsy in certain oral cancer patients.

As part of the agreement, Sinotau is responsible for costs and conduct of clinical studies and regulatory applications to obtain Lymphoseek approval by the China Food and Drug Administration (CFDA). Upon approval, Sinotau will be responsible for all Lymphoseek sales, marketing, market access and medical affairs activities in China and excluding Hong Kong, Macau and Taiwan. Navidea and Sinotau will jointly support certain pre-market planning activities with a joint commitment on clinical and market development programs pending CFDA approval. In addition to the \$300,000 upfront, Navidea is eligible for \$700,000 in milestones up to and through product approval, and an additional \$1.5 million in sales milestones.

"This agreement is part of our goal to make Lymphoseek available to as many physicians and cancer patients around the world as quickly and effectively as possible," said Thomas Tulip, Ph.D., President and Chief Business Officer of Navidea. "We selected Sinotau as a partner in China given their success in developing and filing for market approvals on more than 20 drugs, their pharmaceutical sales and marketing experience, and their established relationships with hospitals and clinicians throughout China."

"Our partnership combines Navidea's expertise in radiopharmaceuticals, clinical development and manufacturing with our extensive development, regulatory, sales, and marketing capabilities," commented Xu Xinsheng, Sinotau President and CEO. "The goal will be to offer a novel radiopharmaceutical to potentially spare patients from unnecessary surgery and which can play a critical role in staging and directing cancer treatment. We look forward to giving physicians this new tool in the fight against the many types of cancers common in China, such as breast, oral, and gastric cancers and contributing to bettering the lives of those afflicted with these conditions."

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.

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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 Manocept™, NAV4694, NAV5001, 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.

About Hainan Sinotau Pharmaceutical Co., Ltd.

Hainan Sinotau Pharmaceutical Co., Ltd. is a pharmaceutical company focused on the registration and commercialization of imported and domestic generic formulations in the mainland China market. Hainan Sinotau commenced operations in 2002 with the purpose of providing access to quality medicines to patients across China; it has experienced strong growth throughout its lifespan with coverage of all of the mainland Chinese market. Hainan Sinotau's strategic focus lies in developing a product portfolio centered on Oncology, Antiretroviral, Central Nervous System and Cardiovascular System therapies in partnership with leading multinational pharmaceutical firms.

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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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