# 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

<u>December 13, 2012</u>	
VIDEA BIOPHARMACEUTICALS, INC	· ·
name of registrant as specified in its char	ter)
001-35076	31-1080091
(Commission File Number)	(IRS Employer Identification No.)
ite 450, Dublin, Ohio	43017
xecutive offices)	(Zip Code)
(614) 793-7500	
me or former address, if changed since last	t report.)
	the filing obligation of the registrant under
ander the Securities Act (17 CFR 230.425) er the Exchange Act (17 CFR 240.14a-12) o Rule 14d-2(b) under the Exchange Act ( o Rule 13e-4(c) under the Exchange Act (	) (17 CFR 240.14d-2(b))
	VIDEA BIOPHARMACEUTICALS, INC. t name of registrant as specified in its char  001-35076 (Commission File Number)  Ite 450, Dublin, Ohio executive offices)  (614) 793-7500  The or former address, if changed since lass filing is intended to simultaneously satisfy action A.2. below):  Inder the Securities Act (17 CFR 230.425) or the Exchange Act (17 CFR 240.14a-12) or Rule 14d-2(b) under the Exchange Act (19 CFR 240.14a-12) or Rule 14d-2(b) under the Exchange Act (19 CFR 240.14a-12) or Rule 14d-2(b) under the Exchange Act (19 CFR 240.14a-12) or Rule 14d-2(b) under the Exchange Act (19 CFR 240.14a-12) or Rule 14d-2(b) under the Exchange Act (19 CFR 240.14a-12)

### Item 1.01. Entry into a Material Definitive Agreement.

On December 13, 2012, Navidea Biopharmaceuticals, Inc. (the "Company") agreed to amend the terms of the Series X Warrant to purchase 8,333,333 shares (the "Shares") of the Company's common stock, \$.001 par value ("Common Stock"), issued by the Company to Platinum-Montaur Life Sciences, LLC ("Montaur") on April 16, 2008, which Series X Warrant was amended and restated on or about July 24, 2009, and then replaced on or about July 2, 2012, to reflect a change in the Company's name (as so amended and replaced the "Series X Warrant"). The Amendment to the Series X Warrant (the "Amendment") provides for the expiration on December 31, 2013, of the term during which Montaur has the right subscribe for and purchase the Shares, as opposed to April 16, 2013, as set forth in the original Series X Warrant.

Additionally, and also effective December 13, 2012, the Company, Montaur, and Platinum Partners Value Arbitrage Fund, L.P. ("Platinum") entered into a waiver agreement (the "Waiver") pursuant to which Montaur and Platinum, as the sole holders of the Company's Series B Convertible Preferred Stock ("Series B Stock"), and the Company, agreed to irrevocably waive the operation of the provisions set forth in Section 9(a) of the Certificate of Designations, Voting Powers, Preferences, Limitations, Restrictions, and Relative Rights of Series B Convertible Preferred Stock (the "Certificate") which provide that all outstanding shares of Series B Stock shall automatically convert into shares of Common Stock on December 31, 2012. The Waiver will remain in effect until December 31, 2013, upon which date all outstanding shares of Series B Stock will automatically convert into Common Stock pursuant to the terms of the Certificate.

The foregoing descriptions of the Amendment and the Waiver are qualified in their entirety by reference to the full text of the Amendment and the Waiver, copies of which are attached hereto as Exhibit 10.1 and Exhibit 10.2, respectively, and each of which is incorporated herein by reference.

#### Item 8.01. Other Events.

On December 18, 2012, the Company issued a press release announcing that it has submitted a Marketing Authorization Application ("MAA") for its investigational radiopharmaceutical Lymphoseek® (technetium Tc 99m tilmanocept) injection, a novel intraoperative lymphatic mapping ("ILM") agent, to the European Medicines Agency. The Company is seeking marketing approval for Lymphoseek in the European Union for use in ILM, a surgical oncology procedure in which lymph nodes draining the area around a tumor are identified and biopsied to determine if cancer has spread to the lymph nodes. The Lymphoseek MAA has proposed the use of the agent in general lymphatic mapping not restricted to any particular solid tumor type.

A copy of the complete text of the Company's December 18, 2012, press release is attached 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
10.1	Amendment to Series X Warrant, dated December 13, 2012, by and between Navidea Biopharmaceuticals, Inc. and Platinum Montaur Life Sciences, LLC.
10.2	Wavier of Automatic Conversion of Series B Convertible Preferred Stock, dated December 13, 2012, by and among Navidea Biopharmaceuticals, Inc., Platinum Montaur Life Sciences, LLC, and Platinum Partners Value Arbitrage Fund, L.P.
99.1	Navidea Biopharmaceuticals, Inc. press release, dated December 18, 2012, entitled "Navidea Biopharmaceuticals Submits Lymphoseek Marketing Authorization Application to European Medicines Agency."

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.

# **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: December 18, 2012

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

# AMENDMENT TO SERIES X WARRANT

This AMENDMENT TO SERIES X WARRANT (this "Amendment"), dated as of December 13, 2012, is made by and between Navidea Biopharmaceuticals, Inc. (f/k/a Neoprobe Corporation), a corporation organized under the laws of Delaware (the "Company"), and Platinum-Montaur Life Sciences, LLC ("Platinum").

### BACKGROUND

WHEREAS, on or about April 18, 2008, the Company issued to Platinum a Series X Warrant (#WX08-001) to Purchase 8,333,333 Shares of the Company's Common Stock, which Series X Warrant was amended and restated on or about July 24, 2009 (#WX08-001A), which Series X Warrant was then replaced on or about July 2, 2012 to reflect a change in the Company's name (#WX08--002) (as so amended and replaced the "Series X Warrant"); and

WHEREAS, as is set forth herein, the Company and Platinum wish to amend certain of the terms of the Series X Warrant.

#### **AGREEMENT:**

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties hereto have agreed as follows.

Amendment to Series X Warrant.

Section 1 of the Series X Warrant is amended to read in its entirety as follows:

- 1. Term. The right to subscribe for and purchase shares of Warrant Stock represented hereby shall commence on April 18, 2008 and shall expire at 5:00 p.m., Eastern Time, on December 31, 2013 (the "Term").
- 2. <u>Continuing Effect</u>. Except as expressly set forth herein, this Amendment shall not alter, modify, amend or in any way affect any of the terms, conditions, covenants, obligations or agreements contained in the Series X Warrant. Any capitalized terms not defined herein shall have that meaning as set forth in the Series X Warrant. This Amendment shall be governed by the laws of the State of New York, without regard to the conflict of law provisions thereof.
- 3. <u>Counterparts</u>. This Amendment may be executed in any number of counterparts, which taken together shall be deemed to constitute one and the same agreement and each of which individually shall be deemed to be an original, with the same effect as if the signature on each counterpart were on the same original.

IN WITNESS WHEREOF, the parties hereto have executed this Amendment on the day and year first above written.

# NAVIDEA BIOPHARMACEUTICALS, INC.

By: /s/ Brent L. Larson

Name: Brent L. Larson

Title: Senior Vice President and CFO

# PLATINUM-MONTAUR LIFE SCIENCES, LLC

By: /s/ Michael Goldberg

Name: Michael Goldberg Title: Portfolio Manager

#### NAVIDEA BIOPHARMACEUTICALS, INC.

425 Metro Place North, Suite 450 Dublin, Ohio 43017

December 13, 2012

Platinum Montaur Life Sciences, LLC 152 West 57th Street, 4th Floor New York, New York 10019 Attention: Dr. Michael Goldberg

Re: Automatic Conversion of Series B Convertible Preferred Stock

#### Ladies and Gentlemen:

Reference is hereby made to that certain Certificate of Designations, Voting Powers, Preferences, Limitations, Restrictions, and Relative Rights of Series B Convertible Preferred Stock (the "Series B Certificate") of Navidea Biopharmaceuticals, Inc. (the "Company"), Section 9(a) of which provides, among other things, that all outstanding shares of Series B Preferred Stock shall automatically convert into Common Stock at the Conversion Rate on December 31, 2012 (the "December 2012 Automatic Conversion"), subject to the limitations set forth therein. Sections 3 and 10 of the Series B Certificate further provide that the powers, designations, preferences and rights of the Series B Preferred Stock may be amended, altered, changed or repealed with the written consent of not less than a majority of the then outstanding shares of Series B Preferred Stock. Capitalized terms used herein and not otherwise defined shall have the meanings ascribed to them in the Series B Certificate.

Platinum-Montaur Life Sciences, LLC and Platinum Partners Value Arbitrage Fund, L.P. (hereinafter referred to as "Platinum-Montaur"), as the sole holders of Series B Preferred Stock, and the Company, hereby agree that the provisions of the Series B Certificate providing for the December 2012 Automatic Conversion shall be deemed irrevocably waived by each of the Company and Platinum-Montaur through December 31, 2013, whereupon all outstanding shares of Series B Preferred Stock shall automatically convert into Common Stock at the Conversion Rate on that date, subject to the beneficial ownership limitations set forth in the Series B Certificate. The execution of this letter agreement by Platinum-Montaur and the Company shall only constitute a waiver of the operation of the December 2012 Automatic Conversion provisions contained in of the Series B Certificate, and will not operate as a waiver by Platinum Montaur or the Company of any other power, right or privilege under the Series B Certificate or preclude the further exercise thereof or of any other right power or privilege.

Please countersign this letter in order to evidence Platinum-Montaur's agreement with this Agreement.

[Signature page follows]

# NAVIDEA BIOPHARMACEUTICALS, INC.

By: /s/ Brent L. Larson

Name: Brent L. Larson

Title: Senior VP and Chief Financial Officer

Acknowledged and agreed as of the date set forth above:

# PLATINUM MONTAUR LIFE SCIENCES, LLC

By: Platinum Partners Value Arbitrage Fund, L.P.

By: Platinum Management (NY), LLC, General Partner

By: /s/ Michael Goldberg

Name: Michael Goldberg Title: Portfolio Manager

# PLATINUM PARTNERS VALUE ARBITRAGE FUND, L.P.

By: Platinum Management (NY), LLC, General Partner

By: /s/ Michael Goldberg

Name: Michael Goldberg Title: Portfolio Manager



#### Press Release

# Navidea Biopharmaceuticals Submits Lymphoseek Marketing Authorization Application to European Medicines Agency

DUBLIN, OHIO, December 18, 2012 – Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB), a biopharmaceutical company focused on precision diagnostic radiopharmaceuticals, today announced that it has submitted a Marketing Authorization Application (MAA) for its investigational radiopharmaceutical Lymphoseek<sup>®</sup> (technetium Tc 99m tilmanocept) injection, a novel intraoperative lymphatic mapping (ILM) agent, to the European Medicines Agency (EMA).

"The submission of the Lymphoseek MAA marks a significant milestone for Navidea as we continue our global development and commercialization efforts for Lymphoseek. It is also important to note that, as part of the normal MAA filing process, the EMA required good manufacturing practices (GMP) pre-submission inspections at the Lymphoseek contract manufacturing facilities. These inspections were recently successfully completed by independent auditors from the European Union (EU), thereby enabling our MAA filing," commented Dr. Mark Pykett, President and CEO of Navidea. "We are encouraged by these positive pre-submission manufacturing audits which we believe bode well for Lymphoseek's ultimate commercialization. We are prepared to support the ongoing EMA approval process and to continue our pre-commercialization activities as we confidently anticipate U.S. approval of Lymphoseek in the coming months."

Navidea is seeking marketing approval for Lymphoseek in the EU for use in ILM, a surgical oncology procedure in which lymph nodes draining the area around a tumor are identified and biopsied to determine if cancer has spread to the lymph nodes. The Lymphoseek MAA has proposed the use of the agent in general lymphatic mapping not restricted to any particular solid tumor type. According to the European Union's FACT Public Health Programme Fighting Against Cancer, approximately 2.2 million new cases of solid tumor type cancers are expected to be diagnosed in the EU.

Dr. Pykett added, "For patients and medical professionals, ILM is part of the standard of care in Europe for certain solid-tumor cancers, including breast cancer and melanoma and is actively being investigated in other cancer types such as head and neck cancer and prostate cancer. Lymphoseek is specifically designed to target key predictive lymph nodes through a receptor-based mechanism, which we believe may lead to enhanced diagnostic accuracy through rapid injection site clearance, stable target binding, lower false negative results, and better cancer staging of patients in ILM procedures while affording scheduling flexibility."

## About the Lymphoseek MAA Submission

The Marketing Authorization Application submission is supported by a comprehensive clinical program including the results from two Phase 3 studies of Lymphoseek, NEO3-05 and NEO3-09, performed in patients with either breast cancer or melanoma. The primary endpoint for both the NEO3-05 and NEO3-09 studies was the concordance (or the rate of agreement) on a lymph node count basis of Lymphoseek with vital blue dye. In both of the Phase 3 studies (NEO3-05, NEO3-09), the concordance of Lymphoseek to vital blue dye was highly statistically significant (p<0.0001). Lymphoseek met all primary and secondary endpoints across both studies. In addition, a meta-analysis and pooled-data comparison of results from Navidea's prospective Phase 3 clinical trials of Lymphoseek in patients with breast cancer and melanoma to European colloidal products was included in the MAA filing. The analysis evaluated the performance of Lymphoseek to a meta-analysis of historical, published data for 99m-Tc-labeled colloidal agents considered part of the standard of care in Europe. iii

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In more than 500 subjects receiving Lymphoseek to date, including those studied as a part of the NEO3-05 and NEO3-09 studies, no drug-related serious adverse events or clinically significant drug-related adverse events have been reported.

#### U.S. regulatory status

Navidea is also seeking marketing approval of Lymphoseek in the United States. The U.S. Food and Drug Administration (FDA) has assigned the Lymphoseek New Drug Application (NDA) a Prescription Drug User Fee Act (PDUFA) goal date of April 30, 2013.

# About Lymphoseek®

Lymphoseek® (technetium Tc 99m tilmanocept) Injection is a novel, receptor-targeted, small-molecule, investigational radiopharmaceutical used in lymphatic mapping procedures that are performed to help stage cancers such as breast cancer and melanoma. Lymphoseek is designed to identify the lymph nodes that drain from a primary tumor, which have the highest probability of harboring cancer.

Lymphatic mapping is a procedure in which lymph nodes that may contain tumor metastases are identified and biopsied to determine if cancer has spread beyond the primary tumor. Accurate staging of cancer is critical, as it guides therapy decisions and determines patient prognosis and risk of recurrence. According to the American Cancer Society, approximately 229,000 new cases of breast cancer and 76,000 new cases of melanoma are expected to be diagnosed in the United States in 2012.

## **About Lymphatic Mapping**

Lymphatic mapping is a procedure designed to guide lymph node dissection and biopsy procedures. It consists of Intraoperative Lymphatic Mapping (ILM) often accompanied by lymphoscintigraphy. Lymphoscintigraphy is an imaging procedure routinely performed preoperatively to provide guidance on the location of lymph nodes to be biopsied. ILM is a surgical procedure in which lymph nodes draining the area around a tumor are identified and biopsied to determine if cancer has spread to the lymph nodes. These nodes, commonly referred to as "Sentinel Lymph Nodes," are removed and analyzed for the presence of malignant cells. Lymphatic Mapping provides an accurate staging procedure that can help ensure optimal surgical and therapeutic choices, including the avoidance of the morbidity of a complete lymph node dissection for patients in whom the Sentinel Lymph Nodes were found to be free of cancer.

#### About Navidea

Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB) is a biopharmaceutical company focused on the development and commercialization of precision diagnostics and radiopharmaceutical agents. Navidea is actively developing four radiopharmaceutical agent platforms – Lymphoseek<sup>®</sup>, NAV4694, NAV5001 and RIGScan <sup>TM</sup> – to help identify the sites and pathways of undetected disease and enable better diagnostic accuracy, clinical decision-making and, ultimately, patient care. 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.

# NAVIDEA BIOPHARMACEUTICALS ADD – 3

# **Contact:**

Navidea Biopharmaceuticals, Inc. – Brent Larson, Sr. VP & CFO – (614) 822-2330

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<sup>&</sup>lt;sup>i</sup> Coleman, MP, Alexe, DM, Albreht, T, McKee, M, eds. *Responding to the Challenge of Cancer in Europe*. Ljubljana, Slovenia: Institute of Public Health of the Republic of Slovenia, 2008. Project FACT – Fighting Against Cancer Today, funded by the European Union's Public Health Programme.

<sup>&</sup>lt;sup>ii</sup> Sondak, VK, King, DW, Zager, JS, et al. Combined Analysis of Phase III Trials Evaluating [99mTc]Tilmanocept and Vital Blue Dye for Identification of Sentinel Lymph Nodes in Clinically Node-Negative Cutaneous Melanoma, *Ann Surg Oncog.* [DOI 10.1245/s10434-012-2612-z].

iii Tokin, CA, Cope, FO, Metz, WL, et al. The efficacy of tilmanocept in sentinel lymph node mapping and identification in breast cancer patients: a comparative review and meta-analysis of the 99m-Tc-labeled nanocolloid human serum albumin standard of care, *Clinical and Experimental Metastasis*. October 2012, Volume 29, Issue 7, pp681-686. [DOI 10.1007/s10585-012-9497-x].