

NAVIDEA BIOPHARMACEUTICALS, INC.

Form 8-K

July 16, 2014

**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) July 15, 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 1.01. Entry Into a Material Definitive Agreement.

On July 15, 2014, Navidea Biopharmaceuticals, Inc. (the “Company”) entered into agreements relating to the formation of a limited liability company, R-NAV, LLC (R-NAV), which will pursue opportunities for use of the Company’s Manocept™ CD206 macrophage targeting platform technology in diagnosis and treatment of rheumatologic and arthritic diseases. The participants in R-NAV are the Company, Rheumco, LLC, a portfolio company of Essex Woodlands Health Ventures, and third party private investors affiliated with Essex Woodlands. Using a combination of the Company’s Manocept technology and Rheumco’s proprietary Tin-117m radioisotope technology, R-NAV will focus on the development of several diagnostic and therapeutic applications in the arthritis space, each to be conducted in a separate subsidiary of R-NAV:

Subsidiary 1: Detection of rheumatoid arthritis (RA) initially using Tc-99m tilmanocept, commercially known as Lymphoseek® (technetium Tc 99m tilmanocept) Injection,

Subsidiary 2: Combination of the Manocept platform with Tin-117m for detection and treatment of RA

Subsidiary 3: Detection and treatment of human and veterinary osteoarthritis (OA) using the Tin-117m technology, and

Subsidiary 4: Treatment of hemophilic arthropathy (HA), a rare pediatric condition.

The Company has three-year call options to acquire, at its sole discretion, all of the equity of subsidiary 1 prior to the launch of a Phase III clinical trial for its development program, and all of the equity of subsidiary 2 upon completion of radiochemistry and biodistribution studies for its development program. Navidea has an equity ownership position in R-NAV and each of its subsidiaries of approximately 30% on a fully converted basis, subject to potential future dilution.

Both Rheumco and Navidea have contributed licenses for intellectual property and technology to R-NAV in exchange for common units in R-NAV. Each of the licenses has grant-back provisions with respect to inventions and other intellectual property developed in these programs outside of the exclusive fields of use specified in the license.

R-NAV will be initially capitalized through a \$4 million investment from the investors alongside a \$1 million investment from the Company paid over three years, with \$333,334 in cash contributed at inception and a promissory note in the principal amount of \$666,666, payable in two equal installments on the first and second anniversaries of the transaction. The note will bear interest at the applicable federal rate, currently 0.31% per annum. In exchange for its capital and in-kind investment, the Company received 1,000,000 Series A preferred units of R-NAV (“Series A Units”), and an additional 500,000 Series A Units for management and technical services associated with the programs

described above to be performed by the Company for R-NAV pursuant to a services agreement. The Series A Units are convertible into common units at the option of the holder for a conversion price of \$1 per unit, subject to broad-based weighted average anti-dilution rights. R-NAV will be managed by a board of directors of 6 persons, consisting of one person designated by the holders of common units, two persons designated by the holders of the Series A Units, and three persons designated by the holders of the common units and Series A Units voting as a single class (with the holders of the Series A Units voting on an as-converted basis).

The foregoing summary does not purport to be complete and is qualified in its entirety by reference to the Series A Preferred Unit Purchase Agreement and Promissory Note, copies of which are attached as Exhibits 10.1 and 10.2, respectively, to this Current Report on Form 8-K and incorporated herein by reference.

Item 2.03. Creation of a Direct Financial Obligation or an Obligation under an Off-Balance Sheet Arrangement of a Registrant.

The contents of Item 1.01 are incorporated by reference into this item.

Item 8.01. Other Events.

On July 16, 2014, the Company issued a press release announcing its entry into the R-NAV transaction. A copy of the complete text of the Company's July 16, 2014, 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* Series A Preferred Unit Purchase Agreement, dated July 15, 2014, among the Company, R-NAV, LLC, and the other Purchasers named therein.

10.2* Promissory Note, dated July 15, 2014, between the Company as Maker and R-NAV, LLC.

99.1* Navidea Biopharmaceuticals, Inc. press release dated July 16, 2014, entitled "Navidea Joins Essex Woodland's Rheumco to Develop Radiopharmaceuticals for Detection and Treatment of Arthritic Diseases."

* Filed herewith.

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 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 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, Quarterly Reports on Form 10-Q, 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: July 16, 2014 By: /s/ Brent L. Larson

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