

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 5, 2016

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 5, 2016, Navidea Biopharmaceuticals, Inc. (the “Company”) entered into a non-binding letter of intent (“LOI”) with Cardinal Health, Inc. (“Cardinal”) pursuant to which Cardinal intends to acquire the Company’s Lymphoseek product (the “Product”) and certain intellectual property rights and other assets related to the Product (the “Acquired Assets”) and assume certain liabilities associated with the Acquired Assets (the “Proposed Transaction”). The purchase price for the Proposed Transaction shall consist of (i) \$80 million in cash payable at closing (reduced to the extent the amount of transferred Product inventory is less than \$6 million), *plus* (ii) annual earn-out and milestone payments based upon the volume of Product sales. For the first three years, the earn-out payments shall be no less than \$6.7 million per year. In no event will the entire purchase price, including all earn-out payments, exceed \$310,000,000.

As part of the Proposed Transaction, the parties have agreed that simultaneous with the closing, subject to certain conditions, Cardinal will license to the Company (“License Back”), on a perpetual royalty free exclusive basis, certain rights to the Acquired Assets necessary for the Company to (i) develop, manufacture, market, sell and distribute new pharmaceutical and other products so long as such products do not compete with the Product, and (ii) manufacture, market, sell and distribute the Product throughout the world other than in North America.

Also as part of the Proposed Transaction, the Company shall grant to Cardinal five (5) year warrants to purchase up to 10 million shares of the Company’s common stock, par value \$.001 per share, at an exercise price of \$1.50 per share and provide Cardinal with a right of first offer related to the assets covered by the License Back and new products developed by the Company in certain circumstances during the life of the Product’s patents.

The parties intend to negotiate and execute definitive agreements for the Proposed Transaction with customary provisions for a transaction of this size and scope, including representations and warranties regarding the Company, its business, and the Acquired Assets, indemnification of Cardinal by the Company, covenants and closing conditions.

Unless written notice is given to the Company that Cardinal is ceasing further discussions related to the Proposed Transaction, the Company has agreed not to initiate or enter into any discussions with any third party regarding a possible sale of any equity or material assets of the Company or its subsidiaries for a period of thirty days from the date of the LOI. If the Company does not consummate a transaction with Cardinal as contemplated by the LOI and at any time within 180 days of the date of the LOI consummates one or more transactions that, directly or indirectly, result in a sale, license or other transfer of the Product, or all or substantially all of the Company’s assets, then a certain Supply and Distribution Agreement between the Company and Cardinal shall automatically be extended for an additional three year period. The parties have agreed that the provisions described in this paragraph shall be binding.

The closing of the Proposed Transaction is subject to, among other things, the satisfactory completion of due diligence by Cardinal.

A copy of the press release announcing entering into the LOI is attached hereto as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit Number</u>	<u>Exhibit Description</u>
99.1	Press Release dated September 6, 2016.

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, ability to repay debt, the outcome of the CRG litigation, 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 6, 2016

By: /s/ Jed A. Latkin

Jed A. Latkin, Interim Chief Operating Officer



Press Release

FOR IMMEDIATE RELEASE

**Navidea Biopharmaceuticals Enters into Letter of Intent
with Cardinal Health for the Sale of Lymphoseek® in North America**

- Navidea retains rights to non-competitive diagnostic indications and all therapeutic applications -

DUBLIN, OH, September 6, 2016 -- Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB) today announced that it has executed a Letter of Intent ("LOI") with Cardinal Health, Inc. (NYSE:CAH) for the sale of all rights, title and interest to Navidea's Lymphoseek product for all FDA-approved, pending and future oncology diagnostic indications in North America, subject to certain limitations, as well as certain other related assets. Under the terms of the LOI, Navidea would receive \$80 million at closing, with future consideration tied to annual sales of the Lymphoseek product and certain sales-based milestones. Total consideration to Navidea would be capped at \$310 million.

As part of the transaction, Cardinal Health would license back to Navidea a portion of the acquired intellectual property such that Navidea will be able to develop, manufacture, market, sell and distribute new products that do not in any way compete with the current Lymphoseek product, and to continue to manufacture, market, sell and distribute Lymphoseek outside of North America.

Michael M. Goldberg, M.D., Chairman of the Board of Directors, Navidea Biopharmaceuticals, said "This is a significant announcement for all of us at Navidea. This agreement with Cardinal Health will provide significant financial resources for us to repay all outstanding debt to CRG and accelerate the development of our robust pipeline of diagnostic products, which are notably focused on Rheumatoid Arthritis and Cardiovascular disease, as well as our Macrophage Therapeutics pipeline. We have enjoyed a longstanding and successful relationship with Cardinal Health, and we are looking forward to continuing our collaboration."

"Lymphoseek has been an important diagnostic tool for physicians and their patients who are looking for additional clarity when facing potentially life-changing diagnoses," said Tiffany Olson, President of Nuclear Pharmacy Services for Cardinal Health. "We have been Navidea's exclusive US distributor of Lymphoseek for many years. That relationship has set the groundwork for this new agreement, and the Cardinal Health team will continue to market, sell and provide Lymphoseek to those who need it."

The closing of this transaction is subject to the completion of due diligence and the negotiation of definitive documents, among other things, and is dependent upon customary approvals.

Navidea will hold a webcast conference call with investors on Wednesday, September 7, 2016 at 8:30 am ET. Details of the call will be issued later today and will be posted on the Company's Investor website.

About Navidea

Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB) is a biopharmaceutical company focused on the development and commercialization of precision immunodiagnostic agents and immunotherapeutics. Navidea is developing multiple precision-targeted products and platforms including Manocept™ and NAV4694 to help identify the sites and pathways of undetected disease and enable better diagnostic accuracy, clinical decision-making, targeted treatment 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 and in Europe in November 2014. The development activities of the Manocept immunotherapeutic platform will be conducted by Navidea in conjunction with its subsidiary, Macrophage Therapeutics. Navidea's strategy is to deliver superior growth and shareholder return by bringing to market novel products and advancing the Company's pipeline through global partnering and commercialization efforts. For more information, please visit www.navidea.com.

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About Cardinal Health

Cardinal Health, Inc. (NYSE: CAH), is a global integrated healthcare services and products company, providing customized solutions for hospital systems, pharmacies, ambulatory surgery centers, clinical laboratories and physician offices worldwide. The company provides clinically-proven medical products and pharmaceuticals and cost-effective solutions that enhance supply chain efficiency from hospital to home. Cardinal Health connects patients, providers, payers, pharmacists and manufacturers for integrated care coordination and better patient management. Backed by nearly 100 years of experience, with more than 37,000 employees in nearly 60 countries, Cardinal Health ranks among the top 25 on the Fortune 500. For more information, visit cardinalhealth.com, follow @CardinalHealth on Twitter and connect on LinkedIn at [linkedin.com/company/cardinal-health](https://www.linkedin.com/company/cardinal-health).

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, our ability to repay our debt, the outcome of the CRG litigation, 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 The Company undertakes no obligation to publicly update or revise any forward-looking statements.

Source: Navidea Biopharmaceuticals, Inc.

Navidea Biopharmaceuticals Contacts

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