

NAVIDEA BIOPHARMACEUTICALS, INC.

Form 8-K

March 07, 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) March 4, 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.)

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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 March 4, 2014 (the “Effective Date”), Navidea Biopharmaceuticals, Inc. (the “Company”) entered into a Loan and Security Agreement (the “Loan Agreement”) with Oxford Finance LLC (“Oxford”), in its capacity as a lender and as collateral agent for other lenders which may later become parties to the Loan Agreement, pursuant to which Oxford agreed to make a term loan to the Company in an aggregate principal amount of \$30,000,000 (the “Term Loan”). The principal balance of the Term Loan will bear interest from the Effective Date at a per annum rate of interest (based on a 360 day year) equal to 8.5%. The Company will make monthly payments of interest only commencing on April 1, 2014, and continuing on the first calendar day of each successive month thereafter through and including the first calendar day of the month immediately preceding April 1, 2015 (the “Amortization Date,” which may be extended to April 1, 2016, and again to April 1, 2017, if the Company achieves certain milestones associated with the Company’s Lymphoseek product). Commencing on the Amortization Date, and continuing on the first calendar day of each month thereafter, the Company will make consecutive equal monthly payments of principal and interest, in arrears, to the lenders then party to the Loan Agreement based on: (1) the effective rate of interest as determined pursuant to Section 2.3(a) of the Loan Agreement, and (2) a repayment schedule of 48 months if the Amortization Date is April 1, 2015, 36 months if the Amortization Date is April 1, 2016, and 24 months if the Amortization Date is April 1, 2017. All unpaid principal, and accrued and unpaid interest, with respect to the Term Loan is due and payable in full on March 1, 2019. The Company will also make a final payment to the lenders (the “Final Payment”) in an aggregate amount equal to the original principal amount of Term Loan multiplied by: (1) 7.95% if the Amortization Date is April 1, 2015; (2) 8.95% if the Amortization Date is extended to April 1, 2016; or (3) 9.95% if the Amortization Date is extended to April 1, 2017.

In consideration of Oxford’s agreement to make the loan, the Company paid a non-refundable facility fee of \$140,000 to Oxford and reimbursed Oxford for all expenses it incurred in connection with the transaction. Additionally, the Company issued Oxford warrants (the “Series KK Warrants”) to acquire an aggregate 391,032 shares of the Company’s common stock at an exercise price of \$1.918 per share (the “Warrant Exercise Price”). The exercise period for the Series KK Warrants expires seven years from the Effective Date. The Warrant Exercise Price is subject to adjustment pursuant to certain anti-dilution provisions contained in the Series KK Warrants.

The Company may voluntarily prepay the Term Loan in full, upon fifteen business days’ prior written notice to Oxford (in its capacity as collateral agent), without penalty, provided that the Company pays to the lenders on the date of such prepayment an aggregate amount equal to the sum of: (1) all outstanding principal of the Term Loan plus accrued and unpaid interest thereon through the prepayment date; (2) the amount of the Final Payment; (3) a prepayment fee equal to (i) 2% of the principal amount of the Term Loan for a prepayment made on or before March 4, 2015, or (ii) 1% of the principal amount of the Term Loan for a prepayment made after March 4, 2015, but on or before March 4, 2016 (no prepayment fee will apply to a prepayment made after March 4, 2016); and (4) all other obligations that are due and payable, including the expenses of the lenders and interest at the Default Rate (as defined in the Loan Agreement) with respect to any past due amounts.

Pursuant to the terms of the Loan Agreement, the Company granted Oxford, for the benefit of Oxford and other lenders which may later become parties to the Loan Agreement, a security interest in the Company’s personal property

of every kind, including, without limitation, all goods, accounts (including health care receivables), equipment, inventory, contract rights or rights to payment of money, leases, license agreements, franchise agreements, general intangibles (except as noted below), commercial tort claims, documents, instruments (including any promissory notes), chattel paper (whether tangible or electronic), cash, deposit accounts and other collateral accounts, all certificates of deposit, fixtures, letters of credit rights (whether or not the letter of credit is evidenced by a writing), securities, and all other investment property, supporting obligations, and financial assets, and all of the Company's books relating to the foregoing, and any and all claims, rights and interests in any of the above (collectively, the "Collateral"). The Collateral does not include (i) the Company's intellectual property assets, but does include all accounts and all proceeds of the Company's intellectual property assets or (ii) more than 65% of the total combined voting power of all classes of stock entitled to vote the shares of capital stock of any foreign subsidiary of the Company if a pledge of more than 65% of the Shares of such Subsidiary creates an adverse tax consequence to the Company under the U.S. Internal Revenue Code.

The Loan Agreement requires that the Company adhere to certain affirmative and negative covenants, including, without limitation, financial reporting requirements and a prohibition against the incurrence of indebtedness, or creation of additional liens, other than as specifically permitted by the terms of the Loan Agreement. Oxford (in its capacity as collateral agent) may accelerate the payment terms of the Loan Agreement upon the occurrence of certain events of default set forth in the Loan Agreement, which include, without limitation, the failure of the Company to make timely payments of amounts due under the Loan Agreement, the failure of the Company to adhere to the covenants set forth in the Loan Agreement, and the insolvency of the Company.

Also on March 4, 2014, in connection with the Company entering into the Loan Agreement, the Company and Platinum-Montaur Life Sciences, LLC (“Platinum”) entered into a Second Amendment (the “Second Platinum Amendment”) to the Loan Agreement (the “Platinum Loan Agreement”) between the Company and Platinum, dated July 25, 2012, as amended by the Amendment to Loan Agreement dated June 25, 2013. Platinum and Oxford also entered into a Subordination Agreement, dated March 4, 2014 (the “Subordination Agreement”), which the Company consented to and acknowledged, providing for the subordination of the Company’s indebtedness under the Platinum Loan Agreement to the Company’s indebtedness under the Loan Agreement, among other customary terms and conditions. Contemporaneously with the execution of the Second Platinum Amendment, the Company delivered a Second Amended and Restated Promissory Note, dated March 4, 2014, to Platinum (the “Second Amended Platinum Note”), which amends and restates the Amended Promissory Note, dated June 25, 2013, made by the Company in favor of Platinum in the original principal amount of up to \$35,000,000. The Second Platinum Amendment provides, amongst other things, that the applicable rate of interest under the Platinum Loan Agreement will be the greatest of (i) the United States prime rate as reported in The Wall Street Journal plus 6.75%, (ii) 10.0%, and (iii) the highest rate of interest then payable by the Company pursuant to the Loan Agreement plus 0.125%.

The foregoing description of the terms of the Loan Agreement, the Subordination Agreement, the Second Platinum Amendment, the Second Amended Platinum Note, and the Series KK Warrants, is qualified in its entirety by reference to the text of the Loan Agreement, Subordination Agreement, Second Platinum Amendment, Second Amended Platinum Note, and form of Series KK Warrant, copies of which are attached hereto as exhibits 10.1, 10.2, 10.3, 10.4, and 10.5, respectively, and incorporated herein by reference.

#### **Item 1.02 Termination of a Material Definitive Agreement.**

The contents of Item 1.01 are incorporated by reference into this item. On March 4, 2014, that certain Loan and Security Agreement (the “GECC Loan Agreement”), dated June 25, 2013, among General Electric Capital Corporation (“GECC”), the other financial institutions party thereto as lenders (collectively with GECC the “Lenders”), and the Company, terminated upon the receipt by GECC of a payoff amount of \$26,708,791.67 from the Company; provided that the Company continues to be bound by certain obligations under of the GECC Loan Agreement, including indemnification obligations under Sections 9.6 and 10.4. Under the GECC Loan Agreement, GECC agreed to make a loan to the Company in an aggregate principal amount of \$25,000,000. The principal balance bore interest at a fixed rate equal to 9.83%. The payoff amount paid by the Company in connection with the termination of the GECC Loan Agreement included payments of: (1) \$500,000 as a pre-payment fee; and (2) \$1,000,000 as an end of term “Final Payment Fee.”

#### **Item 2.02. Results of Operations and Financial Condition.**

On March 6, 2014, the Company issued a press release regarding its consolidated financial results for the fourth quarter of 2013, and for the year ended December 31, 2013. A copy of the Company’s March 6, 2014, press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information contained in Item 2.02 of this Current Report on Form 8-K, including exhibit 99.1 attached hereto, shall not be treated as “filed” for purposes of the Securities Exchange Act of 1934, as amended.

**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 2.04. Triggering Events That Accelerate or Increase a Direct Financial Obligation or an Obligation under an Off-Balance Sheet Arrangement.**

The contents of Item 1.01 and 1.02 are incorporated by reference into this item.

**Item 3.02. Unregistered Sale of Equity Securities.**

The contents of Item 1.01 are incorporated by reference into this item. The Series KK Warrants issued to Oxford were issued in a private transaction made in reliance upon exemptions from registration pursuant to Section 4(a)(2) under the Securities Act of 1933, as amended.

**Item 7.01. Regulation FD Disclosure**

In response to a question asked during a conference call held on March 6, 2014, to discuss the Company’s consolidated financial results for the fourth quarter of 2013, and for the year ended December 31, 2013, the Company disclosed that Lymphoseek sales revenue for the first quarter of 2014, through February 28, 2014, had surpassed the Company’s sales revenue for the fourth quarter of 2013.

The information contained in Item 7.01 of this Current Report on Form 8-K is being furnished and shall not be deemed to be “filed” for the purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of such section, nor shall such information be deemed incorporated by reference in any filing under the Securities Act or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

#### **Item 8.01. Other Events.**

On March 5, 2014, the Company issued a press release announcing that the U.S. Food and Drug Administration (the “FDA”) has accepted for review an additional Supplemental New Drug Application (“sNDA”) for the proposed expanded label for Lymphoseek® (technetium Tc 99m tilmanocept) Injection to support broader and more flexible use in imaging and lymphatic mapping procedures, including lymphoscintigraphy and other optimization capabilities. Under the Prescription Drug User Fee Act (“PDUFA”), the FDA has set a target review date for the second Lymphoseek sNDA of October 16, 2014. The two Lymphoseek sNDAs now accepted are derived from a single application submitted to the FDA in December 2013. In assessing the application, the FDA chose to separate the filing in two based on the proposed labeling extensions requested and the scope of information provided. This second sNDA application is aimed at expanding the Lymphoseek label to support more flexible utilization practices for Lymphoseek in lymphatic mapping and lymphoscintigraphy imaging. The first sNDA, aimed at Lymphoseek’s use as a sentinel lymph node detection agent in patients with head and neck cancer, received FDA Fast Track designation and was accepted for priority review, as previously announced, with a PDUFA date target of June 16, 2014. Lymphoseek is currently approved for use in lymphatic mapping procedures performed to aid in the diagnostic evaluation of lymph nodes draining a primary tumor in patients with breast cancer and melanoma. A copy of the complete text of the Company’s March 5, 2014, press release regarding Lymphoseek is attached as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated herein by reference.

On March 5, 2014, the Company issued a press release entitled “Navidea Biopharmaceuticals Closes \$30 Million Loan with Oxford Finance, LLC.” A copy of the complete text of the Company’s March 5, 2014, press release regarding the transaction with Oxford is filed as Exhibit 99.3 to this Current Report on Form 8-K and is incorporated herein by reference.

#### **Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

<u>Exhibit Number</u>	<u>Exhibit Description</u>
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10.1	Loan and Security Agreement, dated March 4, 2014, among Oxford Finance LLC, as collateral agent, the Lenders listed on Schedule 1.1 thereof or otherwise a party thereto from time to time including Oxford in its capacity as a
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Lender, and Navidea Biopharmaceuticals, Inc.

- 10.2 Subordination Agreement, dated March 4, 2014, by and among Platinum-Montaur Life Sciences LLC and Oxford Finance LLC, and consented to and acknowledged by Navidea Biopharmaceuticals, Inc.
- 10.3 Second Amendment to Loan Agreement, dated March 4, 2014, between Navidea Biopharmaceuticals, Inc. and Platinum-Montaur Life Sciences LLC.
- 10.4 Second Amended and Restated Promissory Note, dated March 4, 2014, made by Navidea Biopharmaceuticals, Inc. in favor of Platinum-Montaur Life Sciences LLC
- 10.5 Form of Series KK Warrants to purchase common stock of Navidea Biopharmaceuticals, Inc. issued to Oxford Finance LLC on March 4, 2014.
- 99.1 Press release, dated March 6, 2014, entitled “Navidea Announces Fourth Quarter and Full Year 2013 Results.”
- 99.2 Press release, dated March 5, 2014, entitled “Navidea Announces Acceptance for Review of an Additional sNDA to Further Expand Lymphoseek® Labeling.”
- 99.3 Press release, dated March 5, 2014, entitled “Navidea Biopharmaceuticals Closes \$30 Million Loan with Oxford Finance, LLC.”



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: March 7, 2014 By: /s/ Brent L. Larson  
Brent L. Larson, Executive Vice President and Chief Financial Officer